No.

In the Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

This is one of many suits brought by generic drug manufacturers seeking a declaratory judgment that a generic equivalent will not infringe a patent held by the brand-name manufacturer.

The Question Presented is whether such a suit states a justiciable controversy when, as in this case, the failure to secure a court judgment prohibits the federal government from approving the generic equivalent and the prospect of massive patent liability deters the generic manufacturer from entering the marketplace.

LIST OF PARTIES

All parties in the proceedings below are listed in the caption to this Petition.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

The parent company of Apotex Inc. is Apotex Pharmaceutical Holdings, Inc. The parent company of Apotex Corp. is Apotex Holdings, Inc. There is no publicly-held corporation that owns 10% or more of either Apotex Inc. or Apotex Corp.

TABLE OF CONTENTS

APPENDIX

TABLE OF AUTHORITIES

FEDERAL CASES

FEDERAL STATUTES

OTHER AUTHORITIES

CONSTITUTIONAL PROVISIONS

OPINIONS BELOW

The decision of the United States Court of Appeals for the Federal Circuit (App. 1a)[1] for which review by this Court is sought is available at No. 05-1199, 2005 WL 3457408 (Fed. Cir. Dec. 12, 2005). The decision of the United States District Court for the Southern District of New York that was reviewed by the Federal Circuit (App. 2a-15a) is reported at 385 F. Supp. 2d 187 (S.D.N.Y. 2005).

JURISDICTION

The judgment of the Federal Circuit for which review by this Court is sought was entered on December 12, 2005. This Court has jurisdiction to review the judgment of the Federal Circuit under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Constitution, art. III, § 2, cl. 1 provides in pertinent part:

> The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority; . . . .

(App. 69a.)

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[1] References to "App. ___" are to the Appendix attached hereto, as required under Supreme Court Rule 14.1(i).

21 U.S.C.A. § 355(j)(5)(C)(i)(II) (West Supp. 2005) provides:

> **(C) Civil action to obtain patent certainty-**
>
> **(i) Declaratory judgment absent infringement action-**
>
> * * *
>
> **(II) Filing of civil action-** If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . .

(App. 70a-71a.)

35 U.S.C.A. § 271(e)(5) (West Supp. 2005) provides:

> Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of

> which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(App. 74a.)

STATEMENT OF THE CASE

1. This petition arises from a patent dispute between respondent Pfizer and petitioner Apotex. Pfizer has patents relating to sertraline hydrochloride, which it sells as an anti-depressant under the brand-name Zoloft®, and which generates more than $3 billion in annual sales. Apotex has developed a generic version of Zoloft® that it seeks to market.

Relevant here, Pfizer has listed with the FDA two patents in connection with Zoloft®: one expires in 2006 ("the '518 patent")[2]; the other ("the '699 patent"), which Pfizer has said expires in 2010. Apotex followed the statutory procedure for launching its generic equivalent to Zoloft®. It submitted to the FDA an Abbreviated New Drug Application (ANDA). Apotex represented that it would begin selling its drug after the '518 patent expired in 2006.

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[2] The '518 patent actually expired on December 30, 2005, but Pfizer obtained a 6-month regulatory exclusivity period attaching to that patent. *See* 21 U.S.C. § 355a. That period ends on June 30, 2006.

Apotex further represented that the later-expiring '699 patent would not be infringed or was invalid. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a so-called "Paragraph IV certification").

Pfizer previously has been quite aggressive in defending its intellectual property. It did not, however, sue Apotex precisely in order to prevent the marketing of a generic equivalent to Zoloft®. *See* 21 U.S.C. § 355(j)(5)(B)(iii) and 35 U.S.C. § 271(e)(2)(A) (making the submission of a Paragraph IV certification a statutory act of patent infringement). The failure to resolve the patent controversy specifically created a substantial cloud of uncertainty over Apotex's ability to enter the marketplace because Apotex faced potentially crippling patent liability. In addition, the failure to secure a court judgment of non-infringement or invalidity precluded Apotex as a matter of law from selling its drug until *at least* 180 days after the expiration of the '518 patent.[3]

Congress has enacted a statutory scheme specifically designed to prevent brand-name manufacturers from delaying generic market entry with such tactics. Federal law

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[3] Apotex will be delayed at least 180 days after expiration of the '518 patent. Federal law grants the first generic manufacturer to file an ANDA containing a Paragraph IV certification (in this case, Ivax Pharmaceuticals) the right to sell its products as the only generic competitor for 180 days. *See* 21 U.S.C. § 355(j)(5)(B)(iv). If Apotex secured a judgment that the '699 patent was invalid or not infringed, the expiration of the 180-day period for that patent would begin to run immediately, rather than upon Ivax's first commercial marketing. *Id.* But because, absent a court decision on the '699 patent, Ivax's exclusivity will not begin to run until it begins marketing its product, Apotex could be precluded from marketing far longer than 180 days after the '518 patent expires. This would happen if Ivax, for any reason, decided not to immediately begin marketing its product on June 30, 2006.

provides that Pfizer's submission of the '699 patent to the FDA constitutes a representation that "a claim of patent infringement could reasonably be asserted" based on this patent against a generic competitor. 21 U.S.C. § 355(b)(1). Further, Apotex's filing of its Paragraph IV ANDA constituted a statutory act of patent infringement of the '699 patent. 35 U.S.C. § 271(e)(2)(A). In such circumstances, Congress specifically conferred on the federal courts jurisdiction over a declaratory judgment action by a generic manufacturer (21 U.S.C. § 355(j)(5)(C)(i)(II)) and directed that such suits should be adjudicated to the fullest "extent consistent with the Constitution" (35 U.S.C. § 271(e)(5)).

2. Apotex accordingly brought this declaratory judgment suit against Pfizer in the Southern District of New York alleging that its generic equivalent would not infringe the '699 patent or that the '699 patent was invalid. The district court acknowledged that Pfizer had represented that the '699 patent was enforceable against generic equivalents of Zoloft®, whereas Apotex took the opposite position and submitted an ANDA that constituted a statutory act of patent infringement. (App. 6a-7a.) And the district court did not doubt that Apotex's inability to enter the marketplace based upon a failure to resolve the patent controversy injured Apotex. Indeed, the district court recognized this "gaming of the system" by brand-name manufacturers. (App. 4a.) The practice of companies such as Pfizer of "'parking' the 180-day marketing exclusivity period" has the effect of "indefinitely delaying" generic competition. (App. 5a.) Congress had specifically conferred on generic manufacturers the right to sue, and the obligation of the federal courts to resolve those actions, "[t]o curb these abuses." (*Id.*)

The district court nonetheless held that it was required by Federal Circuit precedent to dismiss the suit for lack of a justiciable case or controversy because Apotex did

not have a "reasonable apprehension" that it would be sued by Pfizer. (App. 12a-15a.)

3. The Federal Circuit had exclusive jurisdiction over Apotex's appeal. 28 U.S.C. § 1295(a)(1). While the appeal was pending, that court decided *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005) (App. 16a-49a), *reh'g denied*, 405 F.3d 990 (Fed. Cir. 2005) (App. 50a-68a), *and cert. denied*, 126 S. Ct. 473 (2005). *Teva* concerned the justiciability of another manufacturer's declaratory judgment action against Pfizer regarding this same drug product – a generic competitor to Zoloft®. Teva, joined by AARP and the Federal Trade Commission as *amicus curiae* (*see* http://www.ftc.gov/ogc/briefs/teva_v_pfizer.pdf), argued that a justiciable case or controversy existed on these recurring facts.

A divided panel of the Federal Circuit, tightening its already rigorous requirement for finding a justiciable case or controversy, held that a court may adjudicate a declaratory judgment action only if the generic competitor faces an "*imminent*" suit by a brand-name manufacturer. *Teva*, 395 F.3d at 1333 (App. 30a). Like the district court in this case, the Federal Circuit in *Teva* did not doubt that a generic manufacturer is directly and immediately injured by this state of affairs. Rather it was dispositive that "Teva virtually concedes that Pfizer will not bring immediate suit" because it "does not wish to expose the patent to the possibility of a noninfringement or invalidity determination." *Id.* at 1333-34 (App. 31a).

The Court simply deemed irrelevant as a matter of law the clear and actual controversy between the parties and the concrete injury suffered by Teva:

> The fact that Teva is disadvantaged from a business standpoint . . . and the fact that Pfizer's decision not to sue Teva creates an

> impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the ~~Hatch~~-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. *It is not the product of a threat of suit by Pfizer. That is the problem that Teva faces in seeking to establish district court jurisdiction.*

395 F.3d at 1338 (App. 40a) (emphasis added). It continued:

> [I]n order to rule in Teva's favor, we would have to hold that the Article III requirement of an actual controversy is satisfied, not because Teva is under an imminent threat of suit by Pfizer, but because the combined circumstances of the Hatch-Waxman scheme and Pfizer's lawful conduct under that scheme have created a situation in which Teva finds itself at a competitive disadvantage . . . . Those circumstances do not amount to an actual controversy between Teva and Pfizer, however.

Id.

Teva, again joined by the FTC as *amicus curiae* (*see* http://www.ftc.gov/ogc/briefs/050208teva.pdf), sought rehearing en banc. The court of appeals denied rehearing by a divided vote and over vigorous dissenting opinions. *Teva*, 405 F.3d at 991-96 (App. 52a-61a) (Gajarsa, J., dissenting); *id.* at 996-99 (App. 61a-68a) (Dyk, J., dissenting).[4]

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[4] In response to Teva's petition for certiorari, Pfizer argued that no controversy existed on the facts of that particular case for a unique

4. Pfizer argued that this appeal was controlled by the Federal Circuit's ruling in *Teva*. The court of appeals agreed and summarily affirmed the judgment dismissing Apotex's suit. (App. 1a.)

REASONS FOR GRANTING THE WRIT

The Federal Circuit's holding that manufacturers such as Apotex are forbidden from filing a declaratory judgment action, pursuant to the Federal law enacted for this precise purpose, merits this Court's review. That ruling cannot be reconciled with this Court's precedents interpreting the case or controversy requirement of Article III. The question is, moreover, of indisputable importance not only to the generic pharmaceutical industry, but also to the public, which relies so heavily on that industry to provide lower-priced versions of life-saving drugs. Accordingly, this Court should grant certiorari. At the very least, the Court should invite the Solicitor General to file a brief expressing the views of the United States on this critically important issue.

I. The Federal Circuit's Decision Elevates The "Reasonable Apprehension" Test To A Constitutional Standard, In Direct Conflict With This Court's Precedents.

The Federal Circuit's decision impermissibly elevates that court's prudential jurisdictional doctrine (the

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reason. After the Federal Circuit's ruling, Teva had agreed to merge with Ivax, such that Teva might never separately market its own generic Zoloft® product. *See* Pfizer's Br. in Opp'n at 10, 11, 23, 25 (No. 05-48). Teva did not dispute that fact. *See* Teva Reply Br. at 4 (No. 05-48). This Court subsequently denied certiorari. *See Teva Pharms. USA, Inc. v. Pfizer*, 126 S.Ct. 473 (2005).

"reasonable apprehension" requirement) to a "constitutional requirement." *See Teva Pharms.*, 395 F.3d at 1335 (App. 33a). That standard cannot be reconciled with a wall of this Court's precedent, which does not impose such a requirement, but rather holds to the contrary, holding that Article III requires no more than a redressible injury-in-fact traceable to the declaratory judgment defendant's conduct.

It is well-established under this Court's controlling precedent that the only prerequisite to jurisdiction under the Declaratory Judgment Act is an "actual controversy" under Article III, which merely requires (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision. *Bennett v. Spear*, 520 U.S. 154, 167 (1997); *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 239-40 (1937); *see also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103-04 (1998); *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 95-96 (1993).

Cardinal Chemical Co. v. Morton International, Inc., for example, addressed the circumstances in which Article III permits a declaratory judgment action with respect to a patent infringement claim. 508 U.S. 83. Recognizing that "a party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy," this Court explained that "[i]n patent litigation, a party may satisfy that burden, and seek a declaratory judgment, even if the patentee has not filed an infringement action." *Id.* at 95. The Court quoted with approval Judge Markey's recognition in *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-35 (Fed. Cir. 1988), that cases such as this present

> the sad and saddening scenario that led to enactment of the Declaratory Judgment Act . . . . In the patent version of that scenario, a patent owner engages in a *danse macabre*,

> brandishing a Damoclean threat with a sheathed sword. . . . Before the Act, competitors victimized by that tactic were rendered helpless and immobile so long as the *patent owner refused to grasp the nettle and sue*. After the Act, those competitors were no longer restricted to an *in terrorem* choice between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises; they could clear the air by suing for a judgment that would settle the conflict of interests. *The sole requirement for jurisdiction under the Act is that the conflict be real and immediate, i.e., that there be a true, actual "controversy" required by the Act.*

Cardinal Chem., 508 U.S. at 95-96 (quoting *Arrowhead Indus. Water*, 846 F.2d at 734-735) (emphasis added).

Indeed, this Court's seminal ruling "upholding the [declaratory judgment] statute" – *Aetna Life Insurance Co.* v. *Haworth*, 300 U.S. 227 (1937) – arose from an indistinguishable context "in which there was no imminent risk of suit because the potential plaintiff declined to sue." *Teva*, 405 F.3d at 996 (App. 63a) (Dyk, J., dissenting). In *Aetna*, an insurer filed a declaratory judgment action regarding its obligations to the policyholders. Aetna sued precisely because the policyholders had "not instituted any action wherein the plaintiff would have an opportunity to prove the absence of the alleged disability." 300 U.S. at 239. This Court held Article III satisfied in light of the "definite and concrete" dispute relating to the parties' "legal rights and obligations." *Id.* at 242. "Where there is such a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged, the judicial function may be

appropriately exercised although the adjudication of the rights of the litigants may not require the award of process or the payment of damages." *Id.* at 241.[5] The criteria set forth by this Court's precedents are easily satisfied in the recurring factual circumstances of this case.

In listing the '699 patent with the FDA, Pfizer formally took the position that generic competitors were subject to suit for infringement of that patent if they marketed prior to its expiration. Apotex seeks to market its generic product before the '699 patent expires, maintaining that its product would not infringe the '699 patent or that the patent is invalid. Apotex currently is injured by virtue of Pfizer's conduct. As an initial matter, Apotex cannot enter the marketplace immediately upon expiration of the '518 patent because FDA cannot approve Apotex's product until Ivax's 180-day exclusivity expires. Should Ivax delay marketing after the '518 patent expires, Apotex's market entry will be further delayed.

Moreover, the very possibility of debilitating patent liability could further delay Apotex from entering the market. Infringement damages calculated on the basis of the enormous monopoly profits associated with blockbuster drugs, such as Zoloft®, would ruin most generic companies. As a result, few generic companies can risk going to market

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[5] Given the statutory command to exercise jurisdiction to the fullest constitutional limits (*see* 35 U.S.C. § 271(e)(5)), the question of whether petitioner's suit satisfies Article III is dispositive of whether it satisfies any statutory or prudential standing requirement. The suggestion of the *Teva* majority that the legislative history supports a narrower reading of the statute, 395 F.3d at 1336-37 (App. 35a-38a), obviously cannot be reconciled with the statutory text. In any event, as discussed in the text, the Federal Circuit's decision is directly contrary to the purposes of the statutory scheme.

before a final judicial resolution of their patent invalidity and/or non-infringement claims. Thus, by refusing to bring suit immediately, brand companies create paralyzing uncertainty that allows these companies to continue selling drugs at monopoly prices while generic companies struggle to obtain the certainty that they need to launch free from fear of patent infringement liability.

Not even the Federal Circuit majority in *Teva* doubted that generic manufacturers such as Apotex suffer an "injury" in the factual scenario at issue here. 395 F.3d at 1338 (App. 40a). That court simply deems irrelevant as a matter of law that the competitor "is disadvantaged from a business standpoint" and "finds itself at a competitive disadvantage." *Id.* That view is insupportable, as Judge Mayer recognized, dissenting in *Teva*:

> Subsequent ANDA applicants suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic drug product free from infringement allegations. By permitting generic companies to bring declaratory judgment claims, Congress has not sought to create a hypothetical injury-in-fact; it has simply recognized the harm that exists absent such relief.

395 F.3d at 1343 (App. 49a).

Notably, the Federal Trade Commission strongly concurs. "The controversy is real and immediate, and is between adverse parties, because Pfizer's conduct creates a bottleneck that just as surely delays [generic competitors] from receiving FDA approval to market a product as if Pfizer had won a preliminary injunction in an infringement suit against [the competitor]." FTC *Teva* En Banc Br. 9. "Absent such a decision," every generic competitor "must

wait for its approval until Ivax has marketed its product for 180 days, which will not occur until December 2006, at the earliest. Thus, the only way that [a competitor] can advance the date of the approval of its product is through this litigation. Absent this action, [the competitor] suffers an injury-in-fact from the lost opportunity to bring its product to market during the 180 days." FTC *Teva* Panel Br. 21-22.

The Federal Circuit originally adopted its "reasonable apprehension" test for "pragmatic" reasons (*EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811-12 (Fed. Cir. 1996)) that simply do not apply here. It sought to "protect[] quiescent patent owners against unwarranted litigation" when they have "done nothing but obtain a patent." *Arrowhead Indus. Water*, 846 F.2d at 736. But "exercising jurisdiction over this action does not force a lawsuit on a 'quiescent' patent-owner." FTC *Teva* Panel Br. 13. To the contrary, the Federal Circuit in *Teva* recognized that Pfizer declined to file suit to prevent generic competition, not because of ambivalence about its patent rights. 395 F.3d at 1333-34, 1338 (App. 31a). The reasonable apprehension test is simply "ill-suited to evaluate an action brought by a subsequent ANDA applicant when that applicant *requires* a court decision so that it can get FDA approval to bring its product to market." FTC *Teva* Panel Br. 12.[6]

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[6] Conflicts between the Federal Circuit's decisions and those of other circuits on "patent issues" also are "useful in identifying questions that merit this Court's attention." *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 839 (2002) (Stevens, J., concurring). This Court accordingly has reviewed Federal Circuit decisions when "other courts have held or assumed" the contrary. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 60 (1998). It therefore bears noting that, in the period that the regional circuits had jurisdiction over patent appeal, they faithfully adhered to this Court's declaratory judgment precedents. The Eighth and District of Columbia Circuits found a jusiticiable

II. The Federal Circuit's Decision Seriously Undermines Congress's Determination to Enhance Generic Pharmaceutical Competition for The Benefit of the American Public.

The Federal Circuit's error is all the more grave because it effectively nullifies an entire statutory scheme. Congress enacted the declaratory judgment provisions invoked by Apotex in this case for the express purpose of permitting suits, such as Apotex's, to go forward in order to ensure that the American public had access to essential, less-expensive generic equivalents.

Before the 1984 Hatch-Waxman Amendments, a generic company had to wait until the patent protecting a drug product expired before it could even begin the lengthy process of preparing its application for submission to the FDA. And because such testing can, and often does, take years, the brand company continued to monopolize that particular drug market years *after* patent expiration as the generic company worked to complete the necessary tests and waited for FDA approval. This unintended period of extended market exclusivity often was referred to as a *de facto* patent term extension. *See generally* Susan Kopp Keyack, *The Drug Price Competition and Patent Term*

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controversy whether the plaintiff had a reasonable apprehension that it will face either an infringement suit or *the threat of one*, a standard met here in light of Pfizer's representation that the '699 patent could be invoked as a basis for patent infringement. *See, e.g., United Christian Scientists v. Christian Science Bd. of Directors, First Church of Christ, Scientist*, 829 F.2d 1152, 1158 n.25 (D.C. Cir. 1987); *Sherwood Med. Indus., Inc. v. Deknatel, Inc.*, 512 F.2d 724, 727-28 (8th Cir. 1975). Notably, these circuits accorded weight to the fact that the patentee has previously brought infringement actions. *See Sherwood Med.*, 512 F.2d at 728; *United Christian Scientists*, 829 F.2d at 1158 n.25.

Restoration Act of 1984: Is It a Healthy Long Term Solution?, 21 RUTGERS L.J. 147, 153-54, 160-61, 165 (1989); Jonathan L. Mezrich, *The Patentability and Patent Term Extension of Lifesaving Drugs: A Deadly Mistake*, 6 J.L. & HEALTH 111, 115-16 (1991/1992).

In 1984 and again in 2003, Congress amended the statute in numerous respects in order to speed generic competition. Congress provided that: (a) a brand-name manufacturer's submission of a patent to FDA constitutes a representation that "a claim of patent infringement could reasonably be asserted" (21 U.S.C. § 355(b)(1)); (b) the filing of an ANDA claiming patent non-infringement or invalidity constitutes a statutory act of patent infringement (35 U.S.C. § 271(e)(2)(A)); (c) federal courts have jurisdiction over such a declaratory judgment action by a generic manufacturer (21 U.S.C. § 355(j)(5)(C)(i)(II); 35 U.S.C. § 271(e)(5)); and (d) such suits should be adjudicated to the fullest "extent consistent with the Constitution" (35 U.S.C. § 271(e)(5)).[7]

Through this scheme, Congress sought to "enable the judicial adjudication upon which the ANDA . . . scheme[] depend[s]." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Congress correctly recognized the substantial national interest in getting "generic drugs into the hands of patients at reasonable prices—fast" (*In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)), and specifically sought to

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[7] Congress also specifically overturned the Federal Circuit's holding that any company that manufactured or used a patented drug while compiling the data necessary to complete an application for FDA approval of a generic drug could be sued for infringement (*see Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861-63 (Fed. Cir. 1984), *superseded by* 35 U.S.C. § 271(e)(1)), which was a principal source of brand name manufacturers' *de facto* patent term extensions.

ensure that "courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies" (H.R. CONF. REP. NO. 108-391, at 836 (2003)). To effectuate that goal, Congress enacted the declaratory judgment provisions to "ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition." 149 CONG. REC. S15,746 (Nov. 24, 2003).

The Federal Circuit's excessively restrictive test for recognizing a justiciable case or controversy accordingly will have far-reaching, negative consequences for generic pharmaceutical companies and the American public that depends upon generic companies like Apotex to bring more affordable drugs to market. Because the Federal Circuit has exclusive jurisdiction over patent disputes, the ruling below governs every attempt in the nation by generic pharmaceutical companies to resolve patent disputes with brand manufacturers. The decision below provides a roadmap for brand manufacturers to preclude litigation of all such disputes. The Federal Circuit's ruling encourages brand companies to delay infringement litigation and, as a result, the market entry of much-needed affordable generic drugs. "No incumbent will ever make the threat [of litigation], if it can simply ride out the term in the listed patent." *Teva*, 405 F.3d at 994-95 (App. 59a) (Gajarsa, J., dissenting).

Thus, the Federal Circuit's decision, by misapplying this Court's precedent, cripples generic competition by leaving generic companies like Apotex under a debilitating cloud of patent uncertainty and outright precludes marketing for a substantial period. Consequently, it seriously undermines congressional efforts to accelerate the introduction of generic drugs and thereby ameliorate the staggering cost of prescription drugs in the United States.

Brand-name manufacturers routinely employ the tactics used by Pfizer in this case to delay competition. A perfect example is Pfizer's conduct with respect to the drug Accupril®, for which Apotex also submitted an ANDA. As in this case, Pfizer asserted its patent against only the first ANDA filer (in that case, Teva). Apotex filed a declaratory judgment action in an effort to obtain patent certainty with respect to its own generic equivalent. A district court dismissed the suit, however, for lack of a case or controversy because Pfizer itself refused to file suit. *See TorPharm, Inc. v. Pfizer Inc.*, No. Civ. 03-990-SLR, 2004 WL 1465756 (D. Del. June 28, 2004). But when another generic competitor (Ranbaxy) entered the market, exposing itself to massive damages, Pfizer promptly filed suit. *See Pfizer Inc. v. Teva Pharms. USA, Inc.*, Case No. 05-cv-00620(DRD) (D.N.J.). While several other companies have FDA approval to begin marketing their own generic Accupril® products, the threat of litigation has significantly delayed generic entry. Thus, brand companies like Pfizer have, in effect, created a new "*de facto*" exclusivity period in direct contravention of Congress's express intent.

The consequences for the American public are substantial. As the Federal Trade Commission advised the Federal Circuit, "declaratory judgment actions serve an important role because the [FTC's] Generic Drug Study showed that *no* generic applicant entered the market prior to a district court decision addressing the patents that, at the time of its application, were listed in the Orange Book." FTC *Teva* Panel Br. 8 n.9 (emphasis added).

The high costs of brand-name prescriptions are a significant barrier in most cases to proper medical treatment for many Americans, particularly the elderly. *See* AARP, *Prescription Drug Costs and the Role of Generic Drugs: Public Opinion Among Americans Aged 45 and Over* 2 (Oct. 1, 2002) ("[N]early one in four Americans 45 and older

(24%) reported *not* being able to afford a prescription drug because no generic version was available."). Because generic drugs are sold for a fraction of the prices of their brand-name counterparts, access to generic pharmaceuticals is "perhaps the single most important route to lower personal and national drug costs during the next decade." Steven Findlay, *Easy Way to Cut Costs of Drugs: Generics*, USA TODAY, May 13, 2004, at 23A.

As the FDA Commissioner has explained, generic drugs "are an increasingly important way to provide the American people with safe, effective and affordable medical treatment." *Generics: FDA Announces Measures to Improve Generic Drug Access*, DRUG WEEK, Mar. 26, 2004, at 239; *see also* National Institute for Health Care Management, *A Primer: Generic Drugs, Patents, and the Pharmaceutical Marketplace* 19 (June 2002) (suggesting that the "advent" of generic anti-depressant drugs "may help rectify" "a persistent under-diagnosis and under-treatment of depression in the U.S."). The cost savings resulting from the availability of generic drugs is inescapable. Indeed, the substitution of generic drugs for brand-name drugs results in billions of dollars in savings each year, without compromising safety or health.[8] Jennifer S. Haas, *et al.*,

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[8] A recent study published in the ANNALS OF INTERNAL MEDICINE, concluded that "broad generic substitution of outpatient prescription drugs could save approximately $8.8 billion, or approximately 11% of drug expenditures for adults . . . in the United States each year." Jennifer S. Haas, *et al.*, *Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997-2000*, 142 ANNALS OF INTERNAL MEDICINE 894 (June 7, 2005); *see also* Food and Drug Administration, *FDA White Paper: New FDA Initiative on "Improving Access to Generic Drugs"* (June 12, 2003), *available at* http://www.fda.gov/oc/initiatives/generics/whitepaper.html

Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997-2000, 142 ANNALS OF INTERNAL MEDICINE 895 (June 7, 2005) (indicating that "[b]road dispensing of generic products would achieve savings without compromising safety," because "[g]eneric drugs are believed to provide therapeutic effects similar to those of their brand-name alternatives"); Food and Drug Administration, *FDA White Paper: New FDA Initiative on Improving Access to Generic Drugs* (June 12, 2003), *available at* http://www.fda.gov/oc/initiatives/generics/whitepaper.html (recognizing that "Americans need generic drugs more than ever" and that "[b]ringing low-cost generic drug alternatives to consumers more quickly can significantly reduce overall health care costs, and increase access to life saving medicines that are just as safe and effective as their brand-name counterparts").

Thus, the decision of the Federal Circuit will have far-reaching negative effects on the American public, as it inevitably and unnecessarily delays access to these lower-cost generic drugs.

(reporting that the average price of a brand-name drug is $72, compared with $17 for its generic counterpart).

CONCLUSION

The petition for certiorari should be granted. Alternatively, the Court should call for the views of the Solicitor General.

Respectfully submitted,

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February 9, 2006

Appendix A – Opinion of the United States Court of Appeals for the Federal Circuit in *Apotex, Inc. v. Pfizer Inc.* (No. 05-1199) Filed December 12, 2005

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 05-1199

APOTEX, INC. and APOTEX CORP., Plaintiffs-Appellants,

v.

PFIZER INC., Defendant-Appellee.

December 12, 2005.

On Appeal from the United States District Court for the Southern District of New York, 04-CV-02539.

Before LINN, DYK, and PROST, Circuit Judges.

Judgment

PER CURIAM

This CAUSE having been heard and considered, it is ORDERED and ADJUDGED:
AFFIRMED. See Fed. Cir. R. 36.

Appendix B – Opinion of the United States District Court for the Southern District of New York in *Apotex, Inc. v. Pfizer Inc.* (No. 04-2539), Granting Defendant's Motion to Dismiss Filed January 3, 2005

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

No. 04 Civ. 2539(DC)

APOTEX, INC and APOTEX CORP., Plaintiffs,

v.

PFIZER INC., Defendant.

January 3, 2005.

CHIN, District Judge.

In this patent case, plaintiffs Apotex, Inc. and Apotex Corp. (together, "Apotex") bring a declaratory judgment action for a determination that their generic drug does not infringe U.S. Patent No. 5,248,699 ("the '699 patent"), held by defendant Pfizer Inc. ("Pfizer"). Pfizer moves to dismiss the action, arguing that the Court lacks subject matter jurisdiction because of the absence of an actual controversy between the parties. For the reasons that follow, the motion is granted and the complaint is dismissed, without prejudice.

BACKGROUND

A. *Regulatory Background*

1. *Hatch-Waxman Amendments*

This dispute arises under a series of amendments to the Federal Food, Drug, and Cosmetic Act of 1938 (the "FDCA"), 21 U.S.C. § 1 *et seq.* The "Hatch-Waxman Amendments," enacted as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), simplified Food and Drug Administration ("FDA") procedures for the approval of generic drugs. *Mova Pharm. Corp. v. Shalala,* 140 F.3d 1060, 1063 (D.C. Cir. 1998). Under the Hatch-Waxman Amendments, companies that want to market generic versions of pioneer drugs may file with the FDA an Abbreviated New Drug Application ("ANDA"), relying on the FDA's prior determinations that the pioneer drug was safe and effective. *See* 21 U.S.C. § 355(j)(2)(A); *see generally Andrx Pharms., Inc. v. Biovail Corp.,* 276 F.3d 1368, 1371 (Fed. Cir. 2002); *Mylan Pharms., Inc. v. Thompson,* 268 F.3d 1323, 1325-27 (Fed. Cir. 2001); *Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd.,* 325 F. Supp. 2d 502 (D.N.J. 2004).

A pioneer drug manufacturer is required to notify the FDA of all patents that cover the pioneer drug. 21 U.S.C. § 355(b)(1), (c)(2). These patents and their expiration dates are listed by the FDA in what is commonly known as the "Orange Book"-the "Approved Drug Products With Therapeutic Equivalence Evaluations." For all applicable patents listed in the Orange Book, ANDA applicants must certify whether the generic drug would infringe the patents. 21 U.S.C. § 355(j)(2)(A)(vii). Specifically, the ANDA applicant may certify that (I) the required patent information has not been submitted to the FDA; (II) the patent has

expired; (III) the patent has not expired but is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the new generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). These are commonly referred to as paragraph I, II, III, and IV certifications. *See generally Andrx Pharms., Inc.*, 276 F.3d at 1371.

If an ANDA applicant makes a paragraph IV certification and the patent holder (the pioneer drug company) sues for patent infringement within forty-five days, the FDA may not approve the ANDA until expiration of the patent, a judicial determination that the patent is invalid or not infringed, or thirty months, whichever is earlier. If the patentee does not sue, the ANDA will be approved. 21 U.S.C. § 355(j)(2)(B)(I), (5)(B)(iii); 21 C.F.R. § 314.95(c)(6).

The first applicant to file an ANDA with a paragraph IV certification is a "first filer," and is eligible for a 180-day exclusivity period during which it is entitled to have the sole generic version of the pioneer drug on the market. 21 U.S.C. § 355(j)(5)(B)(iv). The FDA is prohibited from approving any other ANDA involving the same brand name drug until the end of the exclusivity period, *i.e.*, during that period only the brand name manufacturer and the first filer may market that drug. *Id.* The marketing exclusivity period does not begin immediately upon FDA approval of the first ANDA, but rather upon the earlier of (1) the first commercial marketing of the drug, or (2) the date of a court decision declaring the patent invalid or not infringed. *Id.*

While the Hatch-Waxman framework "has saved billions and billions of dollars for consumers[,] ... there [has been] a gaming of the system" by some brand name drug companies. 149 Cong. Rec. S15563 (daily ed. Nov. 22, 2003) (statement of Sen. Hatch); *see* Congressional Budget Office, "How

Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," 27-31 (July 1998). Some brand name drug manufacturers have succeeded in "parking" the 180-day marketing exclusivity period, indefinitely delaying ANDA approvals and bottlenecking the market. Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration," vi-vii (July 2002). "Parking" occurs when the brand name manufacturer convinces the first filer not to enter the market, often through a settlement agreement concluding a patent infringement suit. *Id.* Absent an intervening court decision, the first filer's failure to enter the market delays the triggering of the 180-day exclusivity period so that it neither begins nor ends, and subsequently filed ANDAs cannot be approved. *Id.*

2. *Medicare Amendments*

To curb these abuses, Congress added another round of amendments to the FDCA in the comprehensive Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Amendments"). Pub. L. No. 108-173, 117 Stat. 2066 (2003). The Medicare Amendments established forfeiture provisions to prevent bottlenecking and revised sections of the patent code authorizing declaratory judgment actions by ANDA filers. *Id.* In particular, Congress provided that "the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction" in any declaratory judgment action by a generic manufacturer who (1) has filed an ANDA with a paragraph IV certification and (2) was not sued by the NDA holder within the forty-five day statutory period. 35 U.S.C. § 271(e)(5).

B. *Facts*

1. *Pfizer*

Pfizer markets Zoloft®, the brand name version of setraline hydrochloride approved by the FDA for the treatment of mood and anxiety disorders. Pfizer has listed Zoloft® in the Orange Book, associating it with the '699 patent and U.S. Patent No. 4,356,518 ("the '518 patent"). The '699 patent will expire on September 28, 2010, and the '518 patent will expire on June 30, 2006.

2. *IVAX*

In 1999, Zenith Goldline Pharmaceuticals, Inc., now known as IVAX, filed the first setraline hydrochloride ANDA. IVAX submitted a paragraph IV certification with respect to the '699 patent, *i.e.*, it asserted that the '699 patent was invalid or not infringed by IVAX's product, and a paragraph III certification with respect to the '518 patent, *i.e.*, it asserted that IVAX will not enter the market until the expiration of the '518 patent on June 30, 2006. As the first filer, IVAX was entitled to a 180-day marketing exclusivity period pursuant to 21 U.S.C. § 355(j)(5)(B)(iv). Pfizer responded within forty-five days of receiving notice of the ANDA, initiating a patent infringement action against IVAX in January 2000. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), the suit automatically suspended FDA approval of the IVAX ANDA for thirty months. The parties reached a settlement in May 2002 that provided that IVAX would receive a license to the '699 patent and may begin marketing setraline hydrochloride by June 30, 2006.

3. *Apotex*

On October 27, 2003, Apotex filed an ANDA seeking the FDA's approval to market its version of setraline hydrochloride. Like IVAX, Apotex filed a paragraph III certification with respect to the '518 patent and a paragraph IV certification with respect to the '699 patent. Pursuant to the Hatch-Waxman framework, the FDA cannot approve the Apotex ANDA until 180 days after IVAX enters the market or a court decision decrees the '699 patent invalid or not infringed, whichever is earlier. If neither event occurs, the Apotex ANDA cannot be approved until September 2010, when the last Zoloft-related patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(ii).

4. *Other ANDA Filers*

In addition to IVAX and Apotex, at least six other generic drug manufacturers have filed ANDAs for setraline hydrochloride; Pfizer has initiated suit against none of them. (Myers Decl. ¶ 9). Two of these companies, Teva Pharmaceuticals USA, Inc. and Dr. Reddy's Laboratories, Ltd., filed ANDA-related declaratory judgment actions against Pfizer, as Apotex has done here. (Def.'s Mem. at 7-8). Both cases were dismissed for lack of subject matter jurisdiction. *Teva Pharms. USA, Inc. v. Pfizer Inc.*, No. 03-CV-10167 (RGS), 2003 WL 22888848, at *1 (D. Mass. Dec. 8, 2003); *Dr. Reddy's Labs., Ltd. v. Pfizer Inc.*, No. 03-CV-726 (JAP), 2003 WL 21638254, at *7 (D.N.J. July 8, 2003).

C. *Procedural History*

Apotex filed its complaint on April 1, 2004. On June 22, 2004, Pfizer moved to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction. Pfizer argues that this Court does not have subject matter jurisdiction

because of the absence of an actual controversy, as required by the Declaratory Judgment Act. 28 U.S.C. § 2201(a). Apotex contends that there is such a controversy. For the reasons that follow, the motion to dismiss is granted.

DISCUSSION

A. *Applicable Law*

1. *Motion to Dismiss Standard*

In considering a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), federal courts "need not accept as true contested jurisdictional allegations." *Jarvis v. Cardillo,* No. 98 Civ. 5793(RWS), 1999 WL 187205, at *2 (S.D.N.Y. Apr. 5, 1999). Rather, a court may resolve disputed jurisdictional facts by referring to evidence outside the pleadings. *Zappia Middle E. Constr. Co. v. Emirate of Abu Dhabi,* 215 F.3d 247, 253 (2d Cir. 2000); *Filetech S.A. v. France Telecom S.A.,* 157 F.3d 922, 932 (2d Cir. 1998). As the party "seeking to invoke the subject matter jurisdiction of the district court," plaintiff bears the burden of demonstrating that there is subject matter jurisdiction in this case. *Scelsa v. City Univ. of New York,* 76 F.3d 37, 40 (2d Cir. 1996).

2. *Subject Matter Jurisdiction*

Subject matter jurisdiction under the Declaratory Judgment Act requires the existence of an actual case or controversy: "The Declaratory Judgment Act permits declaratory relief only in cases presenting 'actual controversies,' ... a requirement that incorporates into the statute the case or controversy limitation on federal jurisdiction found in Article III of the Constitution." *Niagara Mohawk Power Corp. v.*

Tonawanda Band of Seneca Indians, 94 F.3d 747, 752 (2d Cir. 1996) (citing 28 U.S.C. § 2201(a)).

3. *The Reasonable Apprehension Test*

In declaratory judgment actions for patent invalidity or non-infringement, the courts have applied a two-part test to determine whether an "actual controversy" exists:

> There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

Fina Research, S.A. v. Baroid Ltd., 141 F.3d 1479, 1481 (Fed. Cir. 1998). The first prong of this inquiry examines the defendant's conduct, while the second prong focuses on the plaintiff's conduct. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988). This two-part test has become known as the "reasonable apprehension" test.

To determine whether there is a reasonable apprehension that the defendant will sue for patent infringement, courts apply an objective test that focuses on the conduct of the defendant and attempts to ascertain whether a defendant has shown an intent to enforce its patent rights. *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 (Fed. Cir. 1992); *Arrowhead*, 846 F.2d at 736. Such an intent is readily exhibited with express accusations of infringement and threats to bring suit. Explicit threats, however, are not required to create a reasonable apprehension. *EMC Corp. v. Norand Corp.*, 89

F.3d 807, 811 (Fed. Cir. 1996). "In light of the subtleties in lawyer language ... the courts have not required an express infringement charge," *Arrowhead,* 846 F.2d at 736, finding instead that "reasonable apprehension ... may be induced by subtler conduct." *EMC Corp.,* 89 F.3d at 811.

In the absence of overt threats, the "totality of the circumstances" must be considered in evaluating whether a reasonable apprehension of infringement litigation exists. *Arrowhead,* 846 F.2d at 736. In other words, the court must look at the full range of the defendant's conduct and determine whether those actions, considered in context, create a reasonable apprehension. *Consac Indus., Inc. v. Nutramax Labs., Inc.,* No. 97 Civ. 1155(SJ), 1998 WL 229255, at *3 (E.D.N.Y. Mar. 31, 1998).

4. *The Medicare Amendments*

Apotex argues that the reasonable apprehension test is "legally irrelevant," contending that it no longer applies because of the Medicare Amendments passed in 2003. (Pl.'s Mem. at 7). Instead, Apotex argues, the Medicare Amendments expressly authorize an ANDA-filer to bring a declaratory judgment action where, as here, a patentee does not file suit within the forty-five day period. (*Id.* at 8) (citing 21 U.S.C. § 355(j)(5)(C)). It also relies on the amendment to the patent code, which provides that federal courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" over declaratory judgment actions for a declaration of invalidity or non-infringement brought by ANDA applicants who have made a paragraph IV certification. (*Id.*).

Accordingly, Apotex asks the Court to disregard the reasonable apprehension test, and, instead to employ the Article III case or controversy analysis applied in non-patent

cases and in patent cases involving allegations of actual (as opposed to potential) infringement, requiring that "there is (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision." (Pls.' Mem. at 12) (citing *Bennett v. Spear*, 520 U.S. 154, 162, 167 (1997); *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937); and *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003)). Apotex argues that the changes made by the Medicare Amendments require a similar analysis for ANDA-related declaratory judgment actions.

The argument is rejected. The Medicare Amendments do not disturb the Federal Circuit's consistent holding that the constitutional limits of an Article III court's jurisdiction in anticipatory patent infringement declaratory judgment actions are defined by the two-part reasonable apprehension test. *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361 (Fed. Cir. 2004); *Arrowhead*, 846 F.2d at 736; *Torpharm, Inc. v. Pfizer, Inc.*, No. Civ. 03-990-SLR, 2004 WL 1465756, at *7 (D. Del. June 28, 2004) (citing Medicare Amendments and holding reasonable apprehension test is "'consistent with the Constitution'"); *Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd.*, 325 F. Supp. 2d 502, 507-08 (D.N.J. 2004). All of these decisions post-date the Medicare Amendments.

The legislative history of the Medicare Amendments supports the continued application of the reasonable apprehension test. The Conference Report accompanying the Medicare Amendments explains plainly, "the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction." H.R. Conf. Rep. No. 108-391, at 836 (2003).

In response, Apotex points to Congressional testimony reflecting a general intent to eliminate ANDA bottlenecks, arguing that jurisdiction in this case would effectuate that goal. (Pls.' Mem. at 9). While that may be true, it does not show that Congress intended to replace the well-established reasonable apprehension test for declaratory judgment patent cases with the analysis used in non-patent cases.

Accordingly, I apply the two-prong reasonable apprehension test.

B. *Application*

Pfizer does not dispute that the second prong of the reasonable apprehension test has been met. (*See* Def.'s Mem. at 10-20). By filing the ANDA, Apotex committed a "defined act of infringement sufficient to create case or controversy jurisdiction" in patent infringement actions. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). Therefore I address only the first prong-whether Pfizer's conduct gave rise to a reasonable apprehension of suit.

Apotex has not shown that Pfizer created a reasonable apprehension of patent litigation, and thus no actual controversy exists. Therefore this Court does not have subject matter jurisdiction. The Court notes that two District Courts recently reached the same conclusion, in virtually identical cases involving the same patents and products at issue here. *Teva Pharms. USA, Inc. v. Pfizer Inc.*, No. 03-CV-10167 (RGS), 2003 WL 22888848 (D. Mass. Dec. 8, 2003); *Dr. Reddy's Labs., Ltd. v. Pfizer Inc.*, No. 03-CV-726 JAP), 2003 WL 21638254 (D.N.J. July 8, 2003). Likewise, courts in three other similar declaratory judgment cases also dismissed for lack of subject matter jurisdiction. *Torpharm, Inc. v. Pfizer Inc.*, No. Civ. 03-990-SLR, 2004 WL 1465756

(D. Del. June 28, 2004); *Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd.*, 325 F. Supp. 2d 502 (D.N.J. 2004). *Mutual Pharm. Co. v. Pfizer Inc.*, 307 F. Supp. 2d 88 (D.D.C. 2004).

As Pfizer has not explicitly threatened suit (Def.'s Mem. at 15), I consider the totality of the circumstances. *See Arrowhead*, 846 F.2d at 736. Apotex identifies four aspects of Pfizer's conduct that, taken together, allegedly give rise to a reasonable apprehension of suit: (1) Pfizer listed the '699 patent in the Orange Book, (2) Pfizer asserted the '699 patent against IVAX, (3) Pfizer has a history of litigating its patents, and (4) Pfizer has not acknowledged that Apotex's product does not infringe the '699 patent. (Pls.' Mem. at 21-25).

First, Pfizer's listing of the '699 patent in the Orange Book does not contribute to a reasonable apprehension of suit. According to the plain language of the law, an Orange Book listing represents merely that, in certain circumstances, an infringement claim "could" be asserted, but not that one will be asserted. 21 U.S.C. § 355(b)(1). An Orange Book listing imposes no obligation on the patent owner to sue, and does not suggest that a suit is expected or even likely. *Id.; see Torpharm, Inc.*, 2004 WL 1465756, at *9 (finding that an Orange Book listing does not "communicate an intent to sue each and every generic who opts to file an ANDA"). Apotex compares the Orange Book listing to a private letter, noting that reasonable apprehension would exist if Pfizer had sent a letter to Apotex bearing the very same message. (Pls.' Mem. at 22). An Orange Book listing is unlike a private letter and does not carry the same threatening suggestion. An Orange Book listing is directed to the FDA, not any company in particular, and is submitted as a necessary element of the drug application. *See* 21 U.S.C. § 355(a), (b)(1).

Second, Pfizer's suit against IVAX does not contribute to a reasonable apprehension of suit. There was a distinct statutory incentive for Pfizer to sue IVAX: by suing the first filer within forty-five days of notice of the ANDA, Pfizer received an automatic thirty-month delay in the approval of that ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). There is no similar incentive for suing Apotex. Moreover, Pfizer has not sued any of the other ANDA applicants. (Myers Decl. ¶ 9).

Third, Pfizer's history of litigation, though lengthy, is not sufficiently related to this case to create a reasonable apprehension of suit. In cases where courts have found prior litigation sufficiently threatening, either (1) the defendant referenced that litigation in some communication to the plaintiff, *Arrowhead,* 846 F.2d at 733; *Ivoclar Vivadent, Inc. v. Hasel,* No. 02-CV-0316E(F), 2003 WL 21730520, at *1 (W.D.N.Y. June 30, 2003), or (2) there was ongoing litigation between the parties over a series of closely related patents involving the same technology. *Goodyear Tire & Rubber Co. v. Releasomers, Inc.,* 824 F.2d 953 (Fed. Cir. 1987); *Clontech Labs., Inc. v. Life Techs., Inc.,* No. Civ.A. AW-00-1879, 2000 WL 33124811, at *1 (D. Md. Dec. 20, 2000); *SmithKline Beecham Corp. v. Zenith Goldline Pharms., Inc.,* No. Civ.A. 00-CV-1393, 2000 WL 963165, at *1 (E.D. Pa. June 28, 2000). Apotex does not claim that Pfizer sent any threatening communication, but rather it relies on the fact that Pfizer has previously asserted its patent rights against other generic drug companies. (Pls.' Mem. at 24). What is missing from Apotex's argument, however, is an explanation as to how setraline hydrochloride is "essentially the same technology involved" in those actions. *See Goodyear Tire,* 824 F.2d at 954. Companies that profit largely from research and development will frequently find themselves involved in patent infringement litigation; what creates a reasonable apprehension of suit in any given case is

a relationship between that case and some prior litigation. Apotex has not established such a relation here.

Finally, Apotex asks the Court to consider Pfizer's refusal to acknowledge non-infringement, but Apotex does not explain how this behavior is threatening. (Pls.' Mem. at 25). At most, Pfizer's refusal is ambiguous; it does not affirmatively show an intent to sue.

CONCLUSION

For the foregoing reasons, defendant's motion to dismiss for lack of subject matter jurisdiction is granted. The Clerk of the Court shall enter judgment dismissing the complaint without prejudice and close this case.

SO ORDERED.

Appendix C – Opinion of the United States Court of Appeals for the Federal Circuit in *Teva Pharms. USA, Inc. v. Pfizer, Inc* (No. 04-1186) Filed January 21, 2005

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 04–1186

TEVA PHARMACEUTICALS USA, INC., Plaintiff–Appellant,

v.

PFIZER, INC., Defendant–Appellee.

January 21, 2005.

Before MAYER*, CLEVENGER, and SCHALL, Circuit Judges.

SCHALL, Circuit Judge.

Teva Pharmaceuticals USA, Inc. ("Teva") is a manufacturer of generic pharmaceuticals. In July of 2002, it filed an Abbreviated New Drug Application ("ANDA") pursuant to the provisions of the Hatch–Waxman Amendments to the Federal Food, Drug and Cosmetic Act. In its ANDA, Teva sought the approval of the Food and Drug Administration ("FDA") to market its generic version of the drug sertraline hydrochloride. Sertraline hydrochloride is sold under the trade name Zoloft® by Pfizer, Inc. ("Pfizer"). Pfizer holds

* Judge Haldane Robert Mayer vacated the position of Chief Judge on December 24, 2004.

two patents relating to Zoloft®: U.S. Patent No. 4,536,518 (the " '518 patent") and U.S. Patent No. 5,248,699 (the " '699 patent").

When Teva filed its ANDA, it also filed what is called in Hatch–Waxman parlance a "paragraph III certification." In that certification, Teva stated that it would not market its generic drug until the '518 patent expires. Simultaneously, Teva filed a Hatch–Waxman "paragraph IV certification." In that certification, Teva stated that its generic drug did not infringe the '699 patent or, alternatively, that the '699 patent is invalid. The '699 patent expires after the '518 patent. Pursuant to the provisions of the Hatch–Waxman Amendments, Pfizer had forty-five days from the date it received notice of Teva's paragraph IV certification to sue Teva for infringement of the '699 patent, and during that period the statute barred Teva from filing a declaratory judgment action against Pfizer based upon its ANDA.

On January 24, 2003, after Pfizer failed to sue Teva within the forty-five-day period following Pfizer's receipt of notice of the paragraph IV certification, Teva filed a declaratory judgment action against Pfizer in the United States District Court for the District of Massachusetts. In its suit, Teva sought a determination that its generic drug did not infringe Pfizer's '699 patent or that the claims of the '699 patent were invalid. On December 8, 2003, the district court dismissed Teva's suit for lack of jurisdiction. It did so on the ground that Teva had failed to establish that an actual controversy existed between it and Pfizer, as required under the Declaratory Judgment Act, 28 U.S.C. § 2201(a).[1] *Teva Pharms. USA, Inc. v. Pfizer Inc.*, No. 03–CV–10167–RGS, 2003 WL 22888848 (D. Mass. Dec. 8, 2003).

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[1] Unless otherwise indicated, all statutory references are to the 2003 version of the United States Code.

Teva now appeals the decision of the district court, claiming that the court erred as a matter of law in holding that there was no actual controversy between it and Pfizer. The court determined that Teva failed to show that Pfizer had taken actions giving rise to a reasonable apprehension on its part that Pfizer would sue it for infringement of the '699 patent. Having considered the arguments of the parties and several amici,[2] we see no error in the district court's ruling that Teva failed to establish that an actual controversy existed between it and Pfizer. We therefore affirm.

BACKGROUND

I.

A. *The Hatch–Waxman Amendments*

The Hatch–Waxman Amendments were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282). In the Amendments, Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market. *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

In order to speed up the approval process for generic drugs, the Amendments provide that a generic drug manufacturer

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[2] Amicus Curiae Ivax Pharmaceuticals, Inc. submitted a brief in support of Pfizer urging affirmance. Amici Curiae the Federal Trade Commission, the Generic Pharmaceutical Association, and AARP submitted briefs in support of Teva urging reversal.

may submit an ANDA for approval by the FDA, rather than a full New Drug Application ("NDA"). The ANDA may rely on the safety and efficacy studies previously submitted as part of the NDA by demonstrating the generic drug's bioequivalence with the previously approved drug product. *See* 21 U.S.C. § 355(j)(2)(A). Under 35 U.S.C. § 271(e)(1), it is not an act of patent infringement to engage in otherwise infringing acts necessary to prepare an ANDA. However, section 271(e)(2) provides that a generic drug manufacturer infringes a patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent. 35 U.S.C. § 271(e)(2).

The Hatch–Waxman Amendments provide that NDA-holders must notify the FDA of all patents that "claim[ ] the drug for which the [NDA] applicant submitted the application ... and with respect to which a claim of patent infringement could reasonably be asserted ...." 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists such patents in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). As part of the approval process, an ANDA applicant must make one of four certifications with respect to each patent listed in the Orange Book that claims the drug for which it is seeking approval: (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). These are commonly referred to as paragraph I, II, III, and IV certifications.

Upon filing a paragraph IV certification as part of an ANDA, an applicant must give notice to the patentee and the NDA holder. The notice must include a detailed statement of the

factual and legal bases for the opinion of the applicant that the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(B)(i). If the patentee files an infringement action within forty-five days after receiving notice of the paragraph IV certification, an automatic thirty-month "stay" goes into effect, during which the FDA cannot approve the ANDA unless the suit is resolved or the patent expires. 21 U.S.C. § 355(j)(5)(B)(iii). During this forty-five day period, the ANDA applicant is barred from filing a declaratory judgment action with respect to the patent at issue. *Id.* If no infringement action is filed during this forty-five day period, the FDA may approve the ANDA. *Id.*

The first ANDA applicant to file a paragraph IV certification enjoys a 180–day period of generic marketing exclusivity, during which the FDA may not approve a subsequent generic applicant's ANDA for the same drug product. 21 U.S.C. § 355(j)(5)(B)(iv). This provision provides an economic incentive for generic manufacturers to challenge the validity of listed patents and to "design around" patents to find alternative, non-infringing forms of patented drugs. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 57 (July 2002). The 180–day exclusivity period typically begins on the date of the first commercial marketing of the drug by the first applicant. 21 U.S.C. § 355(j)(5)(B)(iv). The original Hatch–Waxman Amendments provided that the commencement of the 180–day exclusivity period could also be triggered by "the date of a decision of a court ... holding the patent which is the subject of the certification to be invalid or not infringed."[3] *Id.*

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[3] As discussed in Part I.B., *infra*, in 2003 Congress enacted a more complex set of provisions relating to the 180 day exclusivity period. However, these new provisions do not apply in this case.

B. *The 2003 Medicare Amendments*

Congress recently enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066. The Act was signed into law on December 8, 2003. Title XI of the Act, entitled "Access to Affordable Pharmaceuticals," makes numerous changes in the Hatch-Waxman Amendments ("Medicare Amendments"). Among the changes is a provision for a "civil action to obtain patent certainty." 21 U.S.C. § 355(j)(5)(C) (Supp. 2004). Pursuant to that provision, if the patentee or NDA-holder does not bring an infringement action within forty-five days after receiving notice of a paragraph IV certification, the ANDA applicant may bring a civil action for a declaratory judgment that the patent at issue is invalid or will not be infringed by the drug for which the applicant seeks approval. *Id.* In exchange, the ANDA applicant must make an offer of confidential access to its ANDA application so that the patentee or the NDA-holder can evaluate possible infringement. *Id.* The Medicare Amendments also provide that when the above circumstances are met, "courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought ... under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5) (Supp. 2004).

Congress also addressed the statutory scheme surrounding the 180–day market exclusivity period. Congress replaced the traditional court decision "trigger" with a more complex set of 180–day provisions. *See* 21 U.S.C. § 355(j)(5)(D) (Supp. 2004). However, the Medicare Amendments provide that these new forfeiture provisions are effective only with respect to those applications filed after December 8, 2003,

for which no paragraph IV certification was made before December 8, 2003. Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1102(b), 117 Stat. at 2460. Thus, the new forfeiture provisions do not apply in this case.

II.

A. *The '518 and '699 Patents*

Pfizer's '518 patent, which expires on June 30, 2006, is directed to the chemical compound sertraline hydrochloride, which is useful for the treatment of mental depression and anxiety disorders.[4] Sertraline hydrochloride operates by interacting with serotonin, a chemical messenger that participates in the transmission of nerve impulses in the brain. Sertraline hydrochloride works to selectively block the uptake of serotonin by synaptic cells, thus reducing its re-entry into nerve cells and allowing serotonin levels between nerve cells in the brain to build up. Pfizer's '699 patent, which expires on September 28, 2010, is directed to a novel crystalline form of sertraline hydrochloride and to a method for preparing it.[5] The commercial embodiment of the '518 and '699 patents is the drug Zoloft®, a hugely successful drug which has been approved by the FDA for treatment of mood and anxiety disorders. According to Pfizer's Annual

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[4] The '518 patent was due to expire on December 30, 2005. However, the district court opinion explains that the FDA granted Pfizer a six-month pediatric exclusivity extension for the drug, pursuant to 21 U.S.C. § 355a, making June 30, 2006 the effective expiration date of the patent.

[5] The district court's opinion recites that the '699 patent expires on September 29, 2010. We note that the electronic version of the Orange Book located on the FDA's website indicates that the '699 patent also was granted a six-month pediatric exclusivity extension.

Report, Zoloft® generated revenues for the company in excess of $2 billion in 2002.

B. *Ivax Pharmaceuticals USA, Inc.'s ANDA filing relating to generic sertraline hydrochloride tablets*

Ivax Pharmaceuticals USA, Inc. ("Ivax") is a manufacturer of generic pharmaceuticals. In 1999, Ivax, then known as Zenith Goldline Pharmaceuticals, Inc., submitted an ANDA to the FDA for its generic version of sertraline hydrochloride. Since Pfizer had listed both the '518 and '699 patents in the Orange Book in connection with its NDA for Zoloft® tablets, Ivax was required to file a certification with respect to each patent as part of its ANDA. Ivax filed a paragraph III certification as to the '518 patent, stating that it was not seeking to market its generic version of sertraline hydrochloride prior to the expiration of the patent. Simultaneously, Ivax filed a paragraph IV certification as to the '699 patent, stating that its generic drug did not infringe the '699 patent, or alternatively, that the '699 patent was invalid.

Within forty-five days of its receipt of notice of Ivax's paragraph IV certification, Pfizer filed suit against Ivax for infringement of the '699 patent in the United States District Court for the District of New Jersey. *Pfizer, Inc. v. Ivax Pharms. Inc.*, Nos. 00–408, 01–6007 (D.N.J. Jan. 1, 2000). In 2002, Pfizer and Ivax entered into a settlement agreement whereby Pfizer agreed to grant Ivax a royalty-bearing license on the '699 patent until its expiration in 2010. As a consequence of the agreement, Ivax is in a position to begin marketing its generic version of Zoloft® immediately upon expiration of the '518 patent on June 30, 2006.

As the first-filer of an ANDA for the generic version of Zoloft®, Ivax is entitled, under 21 U.S.C. § 355(j)(5)(B)(iv),

to a 180–day generic market exclusivity period. This 180–day period will be triggered by the earlier of: (1) the first date of commercial marketing by the first generic applicant or (2) a "decision of a court ... holding the patent which is the subject of the [paragraph IV certification] to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(I-II).

C. *Teva's ANDA filing relating to generic sertraline hydrochloride tablets*

As noted, in July of 2002, Teva submitted an ANDA to the FDA for its generic version of Zoloft®. Like Ivax, Teva filed a paragraph III certification as to the '518 patent and a paragraph IV certification as to the '699 patent. Pfizer elected not to file suit against Teva for infringement of the '699 patent within the forty-five days following receipt of notice of Teva's paragraph IV certification, and to date no such suit has been filed.

D. *Teva's declaratory judgment action*

On January 24, 2003, Teva filed a declaratory judgment action in the United States District Court for the District of Massachusetts, seeking a declaration that its generic version of Zoloft® does not infringe the '699 patent and a declaration that the '699 patent is invalid. On March 10, 2003, Pfizer moved to dismiss the action, arguing that the court lacked subject matter jurisdiction because of the absence of an actual controversy, as required by Article III of the Constitution. On December 8, 2003, the court granted Pfizer's motion to dismiss.

In addressing Pfizer's motion, the district court applied the two-part test formulated by this court to determine whether an actual controversy exists in a patent infringement suit. Under that test, there must be both (1) an explicit threat or

other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity. *See Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999). The district court determined that Teva had satisfied the second prong of the test by filing its ANDA for generic sertraline hydrochloride. However, the court concluded that Teva had failed to satisfy the "reasonable apprehension" prong of the test.

Before the district court, Teva argued that Pfizer had created a reasonable apprehension of suit based upon the following considerations: (1) Pfizer had listed the '699 patent in the Orange Book; (2) Pfizer had refused to grant Teva a covenant not to sue; (3) Pfizer had aggressively asserted its patent rights against alleged infringers of other patents; (4) Pfizer sued Ivax, the first generic manufacturer of sertraline hydrochloride; and (5) it was in Pfizer's self-interest to leave a "cloud of litigation" hanging over Teva. With respect to the final consideration, Teva argued that Pfizer's settlement with Ivax gave Pfizer a vested interest in seeing Ivax preserve its 180-day exclusivity period.

The district court rejected Teva's contentions. First, the court noted that a blanket inference that, by listing a patent in the Orange Book, a patentee has declared its intention to sue any potential infringer would virtually eliminate the "reasonable apprehension" prong of the two-part test. Second, the court stated that there is nothing in the Federal Food, Drug, and Cosmetic Act that requires Pfizer to respond one way or another to Teva's request for a covenant not to sue. Third, the court found that Teva's subjective belief that it would be sued because Pfizer sued Ivax does not amount to an explicit

threat indicating the imminence of suit. Finally, the court reasoned that, if anything, Pfizer's self-interest in protecting Ivax's exclusivity period makes the prospect of an immediate lawsuit against Teva even less likely.

Teva timely appealed the district court's decision. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (2000).

ANALYSIS

I.

Our starting point is the Declaratory Judgment Act, 28 U.S.C. § 2201(a), the statute under which Teva filed its suit. The Act provides in relevant part as follows:

> In a case of actual controversy within its jurisdiction ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

The Act, which parallels Article III of the Constitution, "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996). Generally, the presence of an "actual controversy," within the meaning of the Act, depends on "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). Even if there is

an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has substantial discretion to decline that jurisdiction. *Id.; see also Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995) (reaffirming that since its inception, "the Declaratory Judgment Act has been understood to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants"). As we summarized in *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991): "When there is no actual controversy, the court has no discretion to decide the case. When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary."[6]

This court has developed a two-part inquiry to determine whether there is an actual controversy in a suit requesting a declaration of patent non-infringement or invalidity. *EMC Corp.*, 89 F.3d at 811. The inquiry focuses on the conduct of both the patentee and the potential infringer. *Gen–Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir. 2004). There must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity. *Id.; Amana Refrigeration*, 172 F.3d at 855; *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993).

Teva contends on appeal that the district court erred in ruling that it had failed to demonstrate the existence of an actual

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[6] Because the district court dismissed Teva's suit for lack of jurisdiction, it did not reach the stage of exercising its jurisdiction to determine whether to entertain the suit.

controversy between it and Pfizer under our two-part test. Teva argues that it had reasonable, objective grounds to fear that Pfizer would bring an action for infringement of the '699 patent. Teva also argues that the Medicare Amendments establish jurisdiction without regard to the reasonable apprehension prong of the two-part test.

Our task is thus two-fold. First, we must determine whether the district court erred in holding that Teva failed to establish an actual controversy under Article III because it did not demonstrate that it was under a reasonable apprehension that Pfizer would sue it for infringement of the '699 patent. Second, if we determine that the district court did not err in applying the law as it existed when it granted Pfizer's motion to dismiss, we must determine whether, as Teva argues, the effect of the Medicare Amendments was to establish jurisdiction in the district court over Teva's declaratory judgment action. It is to the former question that we turn first.

II.

The district court's dismissal of Teva's declaratory judgment action for lack of jurisdiction presents a question of law that we review without deference. *Gen–Probe*, 359 F.3d at 1379. The parties agree that the second prong (present infringing activity) of our two-part test was met by the filing of Teva's paragraph IV certification with respect to the '699 patent. The case thus turns on the first prong (reasonable apprehension of suit). Teva argues that the district court erred when it determined that Pfizer had not created a reasonable apprehension that it would bring suit against Teva for infringement of the '699 patent.

As it did in the district court, Teva places primary significance on the fact that Pfizer listed the '699 patent in

the Orange Book, thereby representing that the patent "could reasonably be asserted" against any generic sertraline product. Teva takes the position that the requirements of the reasonable apprehension prong of the two-part test are satisfied in virtually every case in which: (1) the NDA applicant has listed a patent in the Orange Book; (2) a generic manufacturer has submitted an ANDA which includes a paragraph IV certification for a drug covered by that patent; and (3) the NDA-holder or patentee has not brought an infringement suit within 45–days of receiving notice of the paragraph IV certification. Teva asserts that the only way a patentee in Pfizer's situation can defeat jurisdiction over an ANDA filer's declaratory judgment action is by affirmatively representing that it will not sue the filer.

Teva's reliance on Pfizer's listing of the '699 patent in the Orange Book is misplaced. The listing of a patent in the Orange Book by an NDA filer is the result of a statutory requirement. Without more, Pfizer's compliance with the Hatch–Waxman listing requirement should not be construed as a blanket threat to potential infringers as far as Pfizer's patent enforcement intentions are concerned. The Orange Book is a listing of patents with respect to which claims of infringement "*could* be reasonably asserted ...." 21 U.S.C. § 355(b)(1), (c)(2) (emphasis added). More is required for an actual controversy than the existence of an adversely held patent, however. *See Capo, Inc. v. Dioptics Med. Prods.*, 387 F.3d 1352, 1355 (Fed. Cir. 2004) ("More is needed than knowledge or notice of an adversely held patent.... The standard is objective, and focuses on whether the patentee manifested the intention to enforce the patent, and would be reasonably expected to enforce the patent against the declaratory plaintiff." (citations omitted)). We are not prepared to hold that listing a patent in the Orange Book evinces an intent to sue any ANDA filer who submits a

paragraph IV certification with respect to the patent.

In support of its contention that it was under a reasonable apprehension that Pfizer would sue it for infringement of the '699 patent, Teva also points to Pfizer's history of defending its patents and its refusal to grant Teva a covenant not to sue. We have stated that, "[w]hen the defendant's conduct, including its statements falls short of an express charge, one must consider the 'totality of the circumstances' in determining whether that conduct meets the first prong of the test." *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988) (quoting *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed. Cir. 1987)). Although relevant to the analysis, neither of the factors upon which Teva relies is dispositive in this case. *See BP Chems.*, 4 F.3d at 980 ("Although a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination, this factor is not dispositive." (internal citation omitted)); *Indium Corp. of Am. v. Semi–Alloys, Inc.*, 781 F.2d 879, 883 (Fed. Cir. 1985) ("The prior patent litigation initiated by Semi–Alloys in 1975, against two other parties unconnected with Indium, was too remote to make Indium's apprehension of further litigation in 1982 reasonable ....").

In order for this case to be one fit for judicial review, Teva must be able to demonstrate that it has a reasonable apprehension of *imminent* suit. Whether there is an "actual controversy" between parties having adverse legal interests depends upon whether the facts alleged show that there is a substantial controversy between the parties "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Maryland Casualty*, 312 U.S. at 273. This requirement of imminence reflects the Article III mandate that the injury in fact be "concrete," and "actual or imminent, not conjectural or hypothetical." *Steel Co. v.*

Citizens for a Better Env't, 523 U.S. 83, 101 (1998). Significantly, Teva virtually concedes that Pfizer will not bring immediate suit for infringement of the '699 patent. According to Teva, Pfizer does not wish to expose the patent to the possibility of a noninfringement or invalidity determination, either of which would trigger Ivax's 180–day exclusivity period before Ivax is in a position to take advantage of the period by beginning commercial marketing of its generic sertraline drug upon expiration of the '518 patent. In any event, Pfizer need not sue Teva immediately, because Teva will not be able to receive FDA approval for its generic sertraline drug prior to the expiration of Ivax's 180–day exclusivity period, which will not begin until expiration of the '518 patent on June 30, 2006. Because Teva is unable to demonstrate a reasonable apprehension of imminent suit on the part of Pfizer for infringement of the '699 patent, we cannot say that the district court erred in its application of the two-part test for determining whether an actual controversy exists in a patent infringement action.

III.

Teva also argues, however, that the Medicare Amendments establish jurisdiction without regard to the reasonable apprehension prong of the traditional two-part test. Although the Medicare Amendments were not in place when this case was before the district court, Congress provided that the provisions dealing with declaratory judgments would "apply to any proceeding ... that is pending on or after the date of the enactment of this Act regardless of the date on which the proceeding was commenced ...." Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1101(c)(1), 117 Stat. at 2456. Since the district court did not issue its opinion until December 8, 2003, the date the Medicare Amendments were enacted, the declaratory judgment provisions apply to this case.

The Medicare Amendments amended 35 U.S.C. § 271(e)(5) so that it reads as follows:

> Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

35 U.S.C. § 271(e)(5) (Supp. 2004). Thus, the Amendments explicitly state that an ANDA filer who submits a paragraph IV certification with respect to a patent listed in the Orange Book may, "consistent with the Constitution," bring a declaratory judgment action with respect to the patent if the patent owner does not bring an infringement action within the statutory forty-five day period.[7]

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[7] Prior to the Medicare Amendments, there was no prohibition against an ANDA filer bringing a declaratory judgment action upon expiration of the forty-five day period.

Teva argues that, in view of the Medicare Amendments, its declaratory judgment suit presents a justiciable controversy under Article III. In making this argument, Teva starts from the premise that, in its words, the reasonable apprehension test serves "primarily prudential not constitutional concerns." (Br. for Teva at 52.) It then posits that, in the Medicare Amendments, Congress directed courts to exercise jurisdiction over declaratory judgment actions such as this to the limits of Article III. Joined by Amicus Curiae the Federal Trade Commission ("FTC"), Teva urges that it has suffered injury independent of the threat of an infringement suit because the 180–day exclusivity period itself has major economic consequences in the case of a drug such as Zoloft®. Teva and the FTC argue that there is a clear connection between this injury and actions already taken by Pfizer. They contend that if Pfizer had not obtained the '699 patent and listed it in the Orange Book, settled its litigation with Ivax, declined to sue Teva, and refused Teva's request for a covenant not to sue, Teva would have the opportunity to gain access to the Zoloft® market during the 180–day period that will follow the expiration of the '518 patent.

As a preliminary matter, we do not agree with Teva that the reasonable apprehension of suit test represents a prudential rule rather than a constitutional requirement. In *EMC*, we squarely stated that we developed the two-part inquiry, of which the reasonable apprehension of suit test is one of the parts, "to determine whether there is an actual controversy in suits requesting a declaration of patent non-infringement or invalidity." 89 F.3d at 811. Teva, nevertheless, points to statements in several of our cases that it argues demonstrate that the test is, in fact, merely a prudential rule. *See Arrowhead*, 846 F.2d at 736 (stating that the two-part test is a "test often useful in evaluating complaints for declaratory judgments in patent cases"); *Fina Oil Chem. Co. v. Ewen*,

123 F.3d 1466, 1470 (Fed. Cir. 1997) ("Satisfaction of th[e] traditional two-part test is not ... a prerequisite to jurisdiction in every possible patent declaratory judgment action. Indeed, the two elements merely assure that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate enough to fulfill the 'actual controversy' requirement."); *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1327 (Fed. Cir. 1998) (stating that the two-part test "contributes to policing the boundary between a constitutional controversy ... and 'a difference or dispute of a hypothetical or abstract character.'" (citation omitted)).

We do not think that the cases cited by Teva support the proposition that the reasonable apprehension of suit prong of our traditional two-part test is not a constitutional requirement. First, there is nothing in *Arrowhead* that supports that proposition. In *Arrowhead*, the court made clear that although the "actual controversy" test in suits requesting a declaration of patent noninfringement or invalidity has been stated in various ways depending on the particular facts at hand, "the test requires two core elements: (1) acts of defendant indicating an intent to enforce its patent; and (2) acts of plaintiff that might subject it or its customers to suit for patent infringement." *Arrowhead*, 846 F.2d at 737. At the same time, the statement from *Fina Oil* upon which Teva relies follows the court's recognition of the traditional two-part test. 123 F.3d at 1470. Under these circumstances, the statement at most suggests that the traditional two-part test is not the only way of determining in all cases that the constitutional requirement of an actual case or controversy has been met.[8] The statement in no way

[8] In *Fina Oil*, the plaintiff sought a declaration that the inventors were properly named on the patent at issue in accordance with 35 U.S.C. § 116 (1994). The statement relied upon by Teva merely reflects that the

suggests that the traditional test does not address the Article III requirement of an actual case or controversy. Finally, the statement Teva quotes from *Hunter Douglas*, 153 F.3d at 1327, is really just another way of saying what we said in *EMC* in expounding on the traditional two-part test: "This court's two-part test for declaratory judgment jurisdiction is designed to police the sometimes subtle line between cases in which the parties have adverse interests and cases in which those adverse interests have ripened into a dispute that may properly be deemed a controversy." 89 F.3d at 811. We would only add that we think this case presents just the sort of situation to which the *EMC* court alluded: Pfizer and Teva certainly have adverse interests. However, for a variety of reasons, their adverse interests have not ripened into an actual controversy.

Neither do we think that in the Medicare Amendments Congress intended to cause courts to alter the present test for determining whether an actual controversy exists in the Hatch–Waxman setting. The plain language of the amended statute—that courts shall have subject matter jurisdiction "to the extent consistent with the Constitution"—compels the conclusion that the Amendments were not meant to automatically bestow district court jurisdiction over actions such as Teva's. The legislative history of the Medicare Prescription Drug, Improvement, and Modernization Act supports this view. In the version of the legislation originally introduced in the Senate (S.1) in the 108th Congress, it was provided that the filing of a paragraph IV certification, and the failure of the patentee or NDA-holder to bring an infringement action within forty-five days after the receipt of notice,

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precise formulation of the constitutional inquiry may vary depending on the facts of a given case.

> shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States in any action brought by the applicant under section 2201 of title 28 for a declaratory judgment that any patent that is the subject of the certification is invalid or not infringed.

Thus, as introduced, the legislation would have embodied the concurring opinion of Judge Gajarsa in *Minnesota Mining and Manufacturing Co. v. Barr Laboratories,* 289 F.3d 775, 784 (Fed. Cir. 2002). Judge Gajarsa suggested that "the two acts of (1) a patentee listing a patent in the Orange Book through the filing of a NDA, and (2) a generic manufacturer filing an ANDA, together meet the case or controversy requirement so as to allow a declaratory judgment action of noninfringement." *Id.* at 791. However, after changes made in conference, the legislation that became law in the 108th Congress (H.R.1) did not contain language automatically conferring subject matter jurisdiction in the district courts anytime a patent is listed in the Orange Book, a paragraph IV certification is filed with respect to the patent, and a patentee fails to bring suit for infringement within forty-five days of receipt of notice of the certification.

The Conference Committee Report on H.R.1 states as follows:

> The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies. The conferees expect courts to apply the "reasonable

apprehension" test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.

Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a "reasonable apprehension" of suit to establish jurisdiction. *See, e.g., Fina Oil and Chemical Co. v. Ewen*, 123 F.3d 1466, 1471 (Fed. Cir. 1997). The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch–Waxman Act.

In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought an infringement suit within the 45 days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. *See, e.g., Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1254 (Fed. Cir. 2002).[9] In any given case, the conferees

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[9] In *Vanguard Research*, while the patentee, Peat, had not made an express threat of litigation, it had (1) sought to enjoin the potential infringer, Vanguard, from production of the potentially infringing technology by filing suit against it on other grounds, (2) had written Vanguard a letter indicating that it no longer had the right to market the potentially infringing technology, and (3) had contacted the U.S. Army and Congress implying to them that Vanguard was using Peat's technology without Peat's permission. 304 F.3d at 1254. The court held

> expect a court may or may not find a reasonable apprehension of suit where these two specific factors are present.

H.R. Conf. Rep. No. 108–391 at 836 (2003).

We conclude that the plain language of the statute, as well as the legislative history, support the conclusion that Congress did not intend for the Medicare Amendments to cause courts to alter the requirement of the two-part test that a declaratory judgment plaintiff must demonstrate a "reasonable apprehension" of suit to establish Article III jurisdiction. Our traditional two-part test remains good law, and, as discussed above, we see no error in the district court's application of the test.

Teva nevertheless points to the statement in the Conference Committee Report that "the conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch–Waxman Act." According to Teva, making the declaratory judgment inquiry turn on the imminence of an infringement suit renders the test subject to manipulation by the patentee, thereby undermining the goals of the Hatch–Waxman Amendments to resolve patent disputes promptly once the issues are joined by the listing of a patent in the Orange Book and the serving of a paragraph IV certification with respect to the patent. Teva argues that these goals are not being served in this case. Teva points out that in view of Pfizer's settlement with Ivax, it is in Pfizer's interest to not expose the '699 patent to litigation, because doing so would raise the possibility of a determination of invalidity or non-infringement, either of which might trigger

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that, based on the totality of circumstances, there was a reasonable apprehension of suit on the part of Vanguard.

the commencement of Ivax's 180–day exclusivity period before the expiration of the '518 patent, in which event the exclusivity period would be useless. Teva asserts, for example, that if Pfizer can avoid triggering Ivax's 180–day exclusivity period until the expiration of the '518 patent, it can expect to enjoy six months selling Zoloft® with only one, royalty-paying generic competitor, Ivax. At the same time, if the '699 patent were held invalid or not infringed, it would mean that during the six-month period following the expiration of the '518 patent on June 30, 2006, Pfizer would face competition in the Zoloft® market, not only from Ivax, but from other generic manufacturers as well. These circumstances, Teva urges, constitute injury to it, because the effect of Pfizer's not bringing suit against Teva is to prevent Teva from challenging the '699 patent and thereby possibly opening the door to its being able to sell generic sertraline hydrochloride during the 180–day exclusivity period following expiration of the '518 patent.

With these same considerations in mind, the FTC states that "while in a 'classic patent declaratory judgment suit,' the ordinary two-part test is appropriate" (Br. for FTC at 17 (quoting *Fina Oil,* 123 F.3d at 1466)), a case such as the present one presents a different situation: "[I]n the Hatch–Waxman regime, a subsequent ANDA applicant may suffer direct legal injury and require judicial relief based not on the threat of an infringement suit, but on the ramifications of actions that a brand-name drug manufacturer has already taken concerning its patents within the regulatory scheme." (Br. for FTC at 17–18.)

We are not persuaded by Teva's and the FTC's arguments. Whether an actual controversy exists between Teva and Pfizer turns on the reasonable apprehension of suit test, which remains in place under the Medicare Amendments, and we have concluded that, under that test, Teva has not

established that an actual controversy exists between it and Pfizer. The fact that Teva is disadvantaged from a business standpoint by Ivax's 180–day exclusivity period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the Hatch–Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. It is not the product of a threat of suit by Pfizer. That is the problem that Teva faces in seeking to establish district court jurisdiction.

If it is the view of Congress that the 180–day exclusivity period for a first ANDA filer creates inequities, it can amend the Hatch–Waxman Amendments accordingly. Until it does so, however, we must apply the statutory scheme as written. *See Reid v. Dep't of Commerce*, 793 F.2d 277, 284 (Fed. Cir. 1986) ("'The remedy for any dissatisfaction with the results in a particular case lies with Congress' and not this court, 'Congress may amend the statute; we may not.'") (quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 576 (1982)). Thus, it is not for us to address any perceived inequities in the statutory scheme by eliminating the reasonable apprehension of suit test in Hatch–Waxman cases. That is what we would have to do in order to rule in favor of Teva in this case. That is because, in order to rule in Teva's favor, we would have to hold that the Article III requirement of an actual controversy is satisfied, not because Teva is under an imminent threat of suit by Pfizer, but because the combined circumstances of the Hatch–Waxman scheme and Pfizer's lawful conduct under that scheme have created a situation in which Teva finds itself at a competitive disadvantage vis-a-vis Ivax. Those circumstances do not amount to an actual controversy between Teva and Pfizer, however.

CONCLUSION

For the foregoing reasons, we agree with the district court that Teva failed to establish that an actual controversy existed between it and Pfizer, as required under the Declaratory Judgment Act, 28 U.S.C. § 2201(a). We therefore affirm the court's dismissal of Teva's declaratory judgment suit for lack of jurisdiction.

AFFIRMED

MAYER, Circuit Judge*, dissenting.

Because the filing of a New Drug Application (NDA) and subsequent listing of a pharmaceutical patent in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book") is conduct giving rise to a reasonable apprehension that an Abbreviated New Drug Application (ANDA) filer and declaratory judgment plaintiff will face a patent infringement suit, I respectfully dissent.

I.

Our traditional two-part test to determine whether an actual controversy exists in a patent infringement suit requires that "(1) the declaratory plaintiff has acted, or has made preparations to act, in a way that could constitute infringement, and (2) the patentee has created in the declaratory plaintiff a reasonable apprehension that the patentee will bring suit if the activity in question continues." *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed.

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* Haldane Robert Mayer vacated the position of Chief Judge on December 24, 2004.

Cir. 1997). Under the Hatch–Waxman Amendments, which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. § 156, 271, 282), part one is satisfied in every instance where an ANDA is filed in accordance with 21 U.S.C. § 355(j), because 35 U.S.C. § 271(e)(2) provides that such a filing constitutes an act of infringement sufficient to trigger a justiciable case or controversy. *See Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676–78 (1990) (determining that the purpose for creating an act of infringement in 35 U.S.C. § 271(e)(2) was to "eliminat[e] the de facto extension at the end of the patent term in the case of drugs, and to enable new drugs to be marketed more cheaply and quickly"); *Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

We have never said that the traditional two-part test must be satisfied in every instance to find a justiciable case or controversy. Conversely, we have consistently held that "there is no specific, all-purpose test" for determining the existence of a case or controversy, either. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735–36 (Fed. Cir. 1988) (describing the traditional two-part test as "often useful in evaluating complaints for declaratory judgments" but not mandatory in every instance). We have clarified that the "[s]atisfaction of this traditional two-part test is not, however, a prerequisite to jurisdiction in every possible patent declaratory judgment action. Indeed, the two elements merely assure that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate enough to fulfill the 'actual controversy' requirement." *Fina Oil*, 123 F.3d at 1470.

Regardless of whether the two-part test is a constitutional necessity or not, the legislative history voices Congress' intent to apply the "reasonable apprehension" portion of the test in determining whether a court may determine the rights of an ANDA filer seeking relief. *See* H.R. Conf. Rep. No. 108–391, at 836 (2003) ("Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction."). "As in all cases our task is to interpret the words of [the statute] in light of the purposes Congress sought to serve." *Chapman v. Houston Welfare Rights Org.*, 441 U.S. 600, 608 (1979).

II.

Because Teva filed an ANDA pursuant to 21 U.S.C. § 355(j) against Pfizer's '699 patent listed in the Orange Book, our application of the traditional test for an "actual controversy" turns solely on whether Pfizer has taken actions that give rise to a reasonable apprehension that it will sue Teva for infringement. The trial court dismissed Teva's declaratory judgment claim saying that no "actual controversy" existed under the Declaratory Judgment Act because, it concluded, Teva faced no "reasonable apprehension" that Pfizer would bring suit against it for infringing the '699 patent. *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, No. 03–CV–10167, 2003 WL 22888848 (D. Mass. Dec. 8, 2003).

The 2003 amendments to the Hatch–Waxman Act provide for declaratory relief when an owner of a patent listed in the Orange Book fails to bring an infringement suit within 45 days after the ANDA is filed. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, PL 108–173, §1117

Stat. 2066 (Dec. 8, 2003) ("Medicare Amendments") (codified in pertinent part at 21 U.S.C. § 355(j)(5)(C)(i)). These Medicare Amendments also give courts the authority to exercise jurisdiction over declaratory judgment actions brought by generic infringers "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5) (2003).

The Declaratory Judgment Act authorizes declaratory relief only in a "case of actual controversy." 28 U.S.C. § 2201 (2000). This requirement is the same as the "case or controversy" requirement of Article III of the Constitution. *See Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha,* 57 F.3d 1051, 1053 (Fed. Cir. 1995) ("The purpose of the declaratory action is to permit a threatened party to resolve its potential liability, but only when the relationship has progressed to an actual controversy, as required by Article III of the Constitution."). The Supreme Court has long held "that whatever else the 'case or controversy' requirement embodied, its essence is a requirement of 'injury in fact.'" *Schlesinger v. Reservists Comm. to Stop the War,* 418 U.S. 208, 218 (1974) (citation omitted).

The Supreme Court also has established criteria for evaluating whether a case passes the constitutional threshold of being a "case or controversy." In *Nashville, Chattanooga & St. Louis Railway Co. v. Wallace,* 288 U.S. 249, 259 (1933), the Court determined that it should "look not to the label which the Legislature has attached to the procedure followed in the state courts, or to the description of the judgment which is brought here for review, in popular parlance, as 'declaratory,' but to the nature of the proceeding which the statute authorizes, and the effect of the judgment rendered upon the rights which the appellant asserts." Similarly, the Court in *Aetna Life Insurance Co. v. Haworth* decided that the federal Declaratory Judgment Act validly conferred jurisdiction on federal courts to issue declaratory

judgments in appropriate cases. 300 U.S. 227 (1937). The Court "observed that the controversy would admit 'of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *Calderon v. Ashmus*, 523 U.S. 740, 746 (1998) (quoting *Aetna*, 300 U.S. at 241). Important to this case, the Court has "thus recognized the potential for declaratory judgment suits to fall outside the constitutional definition of a 'case' in Article III: a claim 'brought before the court(s) for determination by such regular proceedings as are established by law or custom for the protection or enforcement of rights, or the prevention, redress, or punishment of wrongs.'" *Id.* (quoting *Fairchild v. Hughes*, 258 U.S. 126, 129 (1922)). Such is the scheme created by the jurisdictional directives of Congress in the enactment of Hatch–Waxman and corresponding Medicare Amendments—the key issue being whether the courts are capable of achieving a final or conclusive determination that resolves the entire case or controversy.

Finding an actual controversy within the meaning of the Declaratory Judgment Act requires an analysis of the totality of the circumstances of each case. *Gen–Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1379 (Fed. Cir. 2004). The facts alleged must show a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. *Id.* "Although the best evidence of a reasonable apprehension of suit comes in the form of an express threat of litigation, an express threat is not required." *Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1254 (Fed. Cir. 2002) (citations omitted). Determining whether a reasonable apprehension of suit exists in a case controlled by the statutory and regulatory scheme of Hatch–Waxman requires a thorough analysis of the consequences and repercussions of each party's actions.

The most important basis for finding a reasonable apprehension of suit is Pfizer's listing of the '699 patent in the Orange Book. Pfizer's listing constituted an affirmative representation to the FDA and to competitors that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale" of any generic sertraline hydrochloride drug covered by the claims of the '699 patent. 21 U.S.C. § 355(b)(1) (2003). Although the listing in the Orange Book is a standard requirement for filing a NDA, it is a requirement that expresses a party's future intent to enforce its patent rights against those who subsequently file an ANDA and infringe. We have explained that the "reasonable apprehension" test serves to "protect[ ] quiescent patent owners against unwarranted litigation." *Arrowhead,* 846 F.2d at 736. Pfizer is not a defendant that "has done nothing but obtain a patent." *Id.* By listing its patent in accordance with 21 U.S.C. §§ 355(b)(1) & (c)(2), Pfizer has informed the world that the '699 patent likely precludes anyone from marketing a generic sertraline hydrochloride product until it expires.

In evaluating whether there is a controversy, courts must take into account the injury that a generic drug manufacturer suffers when, as a result of actions taken by the brand-name manufacturer, it is delayed from marketing its product. Hatch–Waxman establishes that the first generic applicant to file an ANDA containing a Paragraph IV certification is eligible, in some situations, for 180 days of marketing exclusivity, during which the FDA may not approve subsequent ANDAs for other generic versions of the drug. 21 U.S.C. § 355(j)(5)(B)(iv). Under the 1984 version of the Act, the 180–day period begins to run as of the earlier of: (i) the first day of commercial marketing by the first generic applicant; or (ii) a "decision of a court ... holding the patent which is the subject of the [Paragraph IV certification] to be invalid or not infringed." *Id.* § 355(j)(5)(B)(iv)(I-II). A

court decision has been defined to include any district court decision obtained either by the first ANDA applicant or a subsequent ANDA applicant, through declaratory judgment or otherwise. *See 3M v. Barr Labs., Inc.*, 289 F.3d 775, 778 (Fed. Cir. 2002). If the first ANDA applicant triggers the 180–day period and promptly brings its product to market, then it is permitted, for 180 days, to be the only generic competitor for the name-brand drug. If, instead, a subsequent ANDA applicant triggers the 180–day period by obtaining a court decision, and the first ANDA applicant does not market its drug during that period, then the FDA may approve subsequent ANDAs, and the first ANDA applicant receives no exclusivity.

Although Congress' intention was for Hatch–Waxman to promote competition and speed generic entry into the market, the opposite has occurred as a result of strategies to "park" the 180–day period. Brand-name drug manufacturers may enter into an agreement with the first ANDA applicant whereby the first ANDA applicant agrees to refrain from entering the market for some period of time if the brand-name firm forgoes suing subsequent ANDA applicants during the statutory 45–day period. Such a course of conduct precludes the FDA from approving any subsequent ANDA applicants until: (i) 180 days after the first ANDA applicant enters; (ii) the relevant patent expires; or (iii) a subsequent ANDA applicant can itself trigger the 180–day period. Essentially, the framework of Hatch–Waxman, combined with the conduct of the brand-name manufacturer, creates a cognizable injury to the subsequent generic ANDA filer. The delay created directly injures the subsequent ANDA applicant by depriving it of the opportunity to enter the market. The only way to eliminate this problem is for the subsequent ANDA applicant to bring a declaratory judgment action seeking a court decision of invalidity or noninfringement of the relevant patent.

Taking into account the specific regulatory context of the Hatch–Waxman regime, the "reasonable apprehension" test applied "to the extent consistent with the Constitution" is satisfied by Pfizer's conduct. *See* H.R. Conf. Rep. No. 108–391, at 836 (2003) ("[A] declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction" and the courts should "examine as part of their analysis the particular policies served by the Hatch–Waxman Act."). Cases arising under Hatch–Waxman do not present a classic patent declaratory judgment suit, and accordingly, the reasonable apprehension test should not be applied in the traditional manner. *See Fina Oil*, 123 F.3d at 1470 (discussing classic patent declaratory judgment suits). Typically, a potential competitor is legally free to market its product in the face of an adversely-held patent. In contrast, within the Hatch–Waxman regime, a subsequent ANDA applicant is not free to market-the applicant may suffer direct legal injury and require judicial relief based on the ramifications of actions that a brand-name drug manufacturer has already taken concerning its patents and the likelihood of a future patent suit after the running of the 180–day period.

Against the backdrop of Hatch–Waxman, the totality of Pfizer's conduct must also be considered. *See* H.R. Conf. Rep. No. 108–391, at 836 (2003) ("In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where [an ANDA has been filed with a Paragraph IV certification and the patentee has not brought an infringement suit within 45 days]."). First, Pfizer sued Ivax, the first generic manufacturer of sertraline hydrochloride. This shows both Pfizer's belief that its '699 patent is valid and its intent to assert the patent against infringers. "Related litigation may be evidence of a reasonable apprehension." *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 (Fed. Cir. 1992). Pfizer also has a history

of asserting its patent rights against infringers of other patents. Considering that the '699 patent, which covers the brand name drug Zoloft®, produced nearly 3 billion dollars in profit in 2002, economics and common sense dictate that Pfizer may well bring suit. Finally, Pfizer refused to grant Teva a covenant not to sue for infringement of the '699 patent.

Allowing Teva's declaratory judgment action is consistent with the "case or controversy" requirement of Article III of the Constitution because the suit will achieve a final determination that resolves the entire controversy between Teva and Pfizer. Subsequent ANDA applicants suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic drug product free from infringement allegations. By permitting generic companies to bring declaratory judgment claims, Congress has not sought to create a hypothetical injury-in-fact; it has simply recognized the harm that exists absent such relief. Consequently, under the Hatch–Waxman regime, Teva's injuries are traceable to Pfizer's conduct and those injuries could be redressed by a favorable decision. Therefore, Teva maintains a reasonable apprehension of suit sufficient to confer jurisdiction under the Declaratory Judgment Act.

Appendix D – Opinion of the United States Court of Appeals for the Federal Circuit in *Teva Pharms. USA, Inc. v. Pfizer, Inc* (No. 04-1186), Denying Petition for Panel Rehearing and Rehearing *En Banc* Filed April 4, 2005

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 04-1186

TEVA PHARMACEUTICALS USA, INC., Plaintiff-Appellant,

v.

PFIZER INC., Defendant-Appellee.

April 4, 2005.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, CLEVENGER, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, and PROST, Circuit Judges.

ORDER

A combined petition for panel rehearing and rehearing en banc was filed by the Appellant, and a response thereto was

invited by the court and filed by the Appellee.[1] The petition for rehearing was referred first to the merits panel that heard the appeal. Thereafter, the petition for rehearing en banc, response, and the amici curiae briefs were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:
(1) The petition for panel rehearing is denied.
(2) The petition for rehearing en banc is denied.
(3) The mandate of the court will issue on April 11, 2005.

MAYER, GAJARSA, and DYK, Circuit Judges, would rehear the appeal en banc.

GAJARSA, Circuit Judge, with whom DYK, Circuit Judge, joins, dissents in a separate opinion.

DYK, Circuit Judge, with whom GAJARSA, Circuit Judge, joins, dissents in a separate opinion.

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[1] Amicus curiae briefs were filed by:
1-The Federal Trade Commission.
2-The Generic Pharmaceutical Association.
3-Ivax Pharmaceuticals, Inc.
4-United States Senators Edward M. Kennedy, John S. McCain, and Charles E. Schumer.

GAJARSA, Circuit Judge, with whom DYK, Circuit Judge, joins, dissenting from the order declining rehearing en banc.

The Court has denied the petition to review this case *en banc*. I must respectfully dissent from that denial. This is a critical issue under the Hatch-Waxman Act.[1] The failure of this court by *en banc* action to correct the *Teva* court's decision, 395 F.3d 1324 (Fed. Cir. 2005), allows the statutory procedures to be manipulated by the patent holders to the clear and foreseeable detriment of the generic drug industry.

The *Teva* court's reasonable apprehension analysis is the wrong test for a concrete, actual, or imminent injury in fact when considering the problem of a generic with a second-filed ANDA certification.[2] Article III does not compel it, and the Supreme Court has rejected the doctrinal rigidity that *Teva* introduces. Our cases recognize reasonable apprehension, in the typical patent infringement case, as but a pragmatic attempt to give operational guidance against which patentees can structure their conduct, and control their litigation costs, in a fact-specific area of law. The ANDA

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[1] The Patent Laws and Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271 and 282 (2000)), *as amended by* Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)).

[2] The overall scheme of the Hatch-Waxman Act is described in detail in our decisions in *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) and *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002).

facts correspond to the typical infringement case in name only, and it is this court's constitutional duty to look at those facts in their proper context. The *Teva* court's misguided Article III analysis further thwarts Congress's clear intent to foster, through the detailed provisions of Hatch-Waxman, greater competition in generic pharmaceuticals.

I.

The question is whether Teva has shown a justiciable case or controversy within Article III. Congress unambiguously swept aside any additional limitation on jurisdiction potentially introduced by the Declaratory Judgment Act, 28 U.S.C. § 2201.

> [T]he courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

35 U.S.C.A. § 271(e)(5) (West Supp. 2004), as added by Pub. L. 108-173, 117 Stat. 2457 (Dec. 8, 2003). The law is clear that this justiciability issue has three elements: (1) a concrete, actual or imminent injury in fact; (2) fairly traceable causation between the injury and defendant's conduct; and (3) redressability. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103-04 (1998); *Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982). Only the concrete injury in fact is disputed.

The cases treat the controversy requirements of Article III and § 2201 together and their approach is instructive here. Jurisdiction under § 2201 can be no broader than jurisdiction under Article III, yet the cases show that § 2201 is very broad indeed. Article III is no narrower. *See Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 240 (1937) (§ 2201 "has regard to the constitutional provision and is operative only in respect to controversies which are such in the constitutional sense[.]"). As the Supreme Court recognizes, the § 2201 controversy requirement is highly fact specific.

> The difference between an abstract question and a "controversy" contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy. Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941). The Supreme Court,[3] this court,[4] and our sister

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[3] *See Steel Co.*, 523 U.S. at 103-04; *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 81 (1978) (finding actual case and controversy where plaintiffs would sustain injury from operation of planned nuclear power plant, and injury was redressable by constitutionality challenge to Price-Anderson Act).

[4] *See EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996)

circuits[5] consistently apply this holding by looking to all the circumstances surrounding a controversy.

A.

The *Teva* majority opinion does not, and its reasons for failing to do so are not convincing. In far more difficult factual contexts the courts have nonetheless found "a concrete, actual or imminent injury in fact" satisfying Article III. In *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59 (1978), for example, the appellees challenged the constitutionality of the Price-Anderson Act. By that Act, Congress limited the aggregate tort liability of nuclear power plant operators for a single nuclear "incident." The appellant was a utility that was *constructing* nuclear power plants. The appellees, including persons "who live within close proximity of the *planned* facilities," challenged the statute under the Fifth Amendment. *Id.* at 67 (emphasis added). Their theory was that "*in the event of a nuclear accident* their property *would be* 'taken' *without any assurance* of just compensation." *Id.* at 69 (emphasis added). The court concluded that this theory stated a justiciable Article III controversy. *See id.* at 81 ("[A]ppellees will sustain immediate injury from the operation of the disputed power plants.").

(quoting *Md. Cas.*), *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993) ("There is no simple rule that addresses all shades of relationships between disputants."); *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735-36 (Fed. Cir. 1988) (observing "there is no specific, all-purpose test" for an actual controversy).

[5] *See, e.g., Riva v. Mass.*, 61 F.3d 1003, 1009-10 (1st Cir. 1995); *Kidder, Peabody & Co., Inc. v. Maxus Energy Corp.*, 925 F.2d 556, 562-63 (2d Cir. 1991); *Oneida Tribe of Indians of Wis. v. State of Wis.*, 951 F.2d 757, 760 (7th Cir. 1991).

The breadth of Article III standing in environmental cases sharply contrasts with the *Teva* court's narrow construction in this ANDA context. The Supreme Court has held that a concrete injury in fact, for Article III, is shown where a non-profit's members allege that a polluter's discharges, "and the affiant members' *reasonable concerns about the effects* of those discharges, directly affected those affiants' recreational, aesthetic, and economic interests." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 183-84 (2000) (emphasis added). The Court expressly ruled that conditional statements-that members would use a river for recreation if Laidlaw stopped discharging pollutants into it-sufficed to show concrete injury in fact under Article III. *Id.* at 184. Teva's injury in this case, by comparison, is far more immediate.

The facts showing Teva's "concrete, actual or imminent injury" are far easier to identify. Ivax filed the first ANDA on the active ingredient for Zoloft; Teva filed a subsequent or second ANDA. Teva certified that its proposed formulation would not infringe Pfizer's U.S. Patent No. 5,248,699, or that the patent was invalid. Pfizer had 45 days to sue Teva for this patent infringement, 35 U.S.C. § 271(e)(2)(A), and did not. Although Pfizer had sued Ivax, they settled out of court. Pfizer granted Ivax a royalty bearing license for the '699 patent, preserved Ivax's 180 day statutory exclusivity, and designed a comfortable duopoly set to begin on June 30, 2006 and potentially last 180 days past the '699 patent expiration in 2010. The FDA therefore could not approve Teva's generic drug until 180 days after Ivax's exclusivity expired-when either the '699 patent expired or was invalidated-and without FDA approval Teva could not market its product.

By settling with Ivax, Pfizer leveraged the Hatch-Waxman exclusivity to insulate the '699 patent from any validity challenge. Pfizer also insulated itself from any judicial determination of the metes and bounds of its '699 patent claim scope in relation to a design-around, a determination central to the proper function of our patent system. Because of this insular effect, Pfizer effectively extended-as against all but Ivax-the term of its underlying U.S. Patent No. 4,356,518, which expires on June 30, 2006, to coincide with the '699 patent's later expiration in 2010.[6]

This ties up Teva's investment in its proposed generic until at least 2010, precludes it from testing a potentially weak patent, precludes it from triggering the statutory exclusivity period with a successful validity challenge, and precludes it from introducing an effective design-around, as is its right and as the patent law encourages. The live controversy is found on the face of this bottleneck under the statute.[7] Any of this defines a concrete, actual or imminent injury in fact

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[6] That is, the '518 patent claims the active ingredient in Zoloft. The '699 patent is an improvement. A generic, like Teva, that could design around the '699 but not the '518—or that thought it had found invalidating art for the '699 patent—would need a license to the '518 patent to enter the market, or face an infringement action. Once the '518 patent expired, Teva could confidently enter the market with a compound that did not infringe the '699 patent. But because of the Hatch-Waxman exclusivity, Pfizer insulated the '699 patent from any test in litigation. In practice this extends the '518 patent term until the '699 patent expires.

[7] *Cf. Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 n. 18 (D.C. Cir. 1998) ("It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a 'case or controversy' without demonstrating an immediate risk of being sued.").

within the meaning of Article III, and on that basis Teva states a justiciable controversy under § 2201.

B.

None of these problems can be found in the typical patent infringement context, in which this court has regularly tested immediate injury in fact by the reasonable apprehension test. Consistent with *Maryland Casualty*, this court has never held that Article III required that analysis. Quite to the contrary, this court has repeatedly observed that reasonable apprehension was simply a functional approach to typical patent infringement problems under § 2201. *See EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996) (quoting *Md. Cas.*); *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993) ("There is no simple rule that addresses all shades of relationships between disputants."); *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735-36 (Fed. Cir. 1988) (observing "there is no specific, all-purpose test" for an actual controversy). The purpose of the reasonable apprehension analysis "is to determine whether the need for judicial attention is real and immediate." *BP Chems.*, 4 F.3d at 978. The *Teva* court ignores this precedent and reads general infringement policy considerations into Article III, where they do not belong.

The contextual differences between the second ANDA filer and the typical patent infringement case make the reasonable apprehension test inappropriate for this action. By guiding the patentee's conduct in the typical case, the reasonable apprehension analysis allows the patentee to avoid litigation. Identifying a justiciable controversy in terms of a threat of infringement litigation, the doctrine establishes the circumstances in which the uncertainty of legal rights materially harm a potential infringer in the marketplace. The

injury facing Teva in this case is different in kind, but no less actionable.

Teva's injury does not depend on threats from the incumbent. In view of the statute, the injury exists independent of any threat, and the policy motivation for applying the reasonable apprehension test is completely lacking. There is no sense in the court demanding the incumbent to brandish the threat of infringement actions, even beyond the act of listing a patent in the Orange Book, given a statutory system that encourages the incumbent to do everything possible to prevent its patents from being put in play. No incumbent will ever make the threat, if it can simply ride out the term in the listed patent.[8] From first principles, a fact specific analysis shows that the reasonable apprehension test is not designed for this case.

II.

The language of § 271(e)(5) grants Article III jurisdiction to the maximum extent possible. The statute provides that the courts shall *have* subject matter jurisdiction. The majority's analysis in *Teva* of the legislative history to the 2003 Act[9] seems addressed to this point, but its reasoning is unconvincing.

The statute specifically provides that the courts "shall, to the extent consistent with the Constitution, have subject matter

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[8] *See Minn. Mining and Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775 (Fed. Cir. 2002).

[9] Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)) [hereinafter "2003 Act"].

jurisdiction in any action." The court, therefore, has a Congressional directive to refrain from applying any jurisdictional limitation crafted by the courts or found in § 2201. The *Teva* court overlooks this basic point.

The *Teva* court further focuses on the language originally introduced for § 271(e)(5), which provided that an incumbent's failure to sue within 45 days "shall establish an actual controversy between the applicant and the patent owner." *Teva,* 395 F.3d at 1336. In conference the language was changed to a provision that the courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" over these actions. *Id.* The court concludes that § 271(e)(5) was "not meant to automatically bestow district court jurisdiction over actions such as Teva's." *Id.* This conclusion is contrary to the plain language of § 271(e)(5). The change in language bestowed full Article III jurisdiction and simply recognizes the court's role in declaring when the judicial powers under Article III extend to this action. It does not bear on the proper scope of Article III.

The *Teva* court also focuses on a Committee Report accompanying the modified 2003 Act. The language in the Report cannot contradict the plain language of § 271(e)(5). A legislative enactment cannot limit the judicial power under Article III, and, *a fortiori,* language in a Committee Report that misstates our Article III jurisprudence cannot bind this court.

Ultimately, the idea that § 271(e)(5) suggests a limitation on standing is misplaced, given the plain language of Hatch-Waxman. The statute provides an express mechanism for generics to challenge, with declaratory actions, the claim scope or validity of listed patents. Under this statutory

scheme, it is court challenges by generic drug companies that limit incumbent overreaching by submitting over-inclusive lists of patents applicable to any given branded formulation. Congress's intent to foster early generic market entry precludes any real argument for any limitation. Certainly under the circumstances of this case, Teva's declaratory action is the ideal method to police Pfizer's strategic manipulation of the Hatch-Waxman exclusivity provisions. Delayed resolution of the bottleneck facing Teva serves no purpose, as by then the patents at issue will have expired. There is no basis for precluding this suit on Article III grounds.

III.

The *Teva* court's Article III analysis distorts longstanding Supreme Court jurisprudence and misapplies the decisions of this court. Teva has presented a justiciable controversy, and the courts should decide it. Worst of all, the *Teva* court's Article III analysis forestalls legislative correction. The court should have corrected this error *en banc*. I respectfully dissent from the refusal to do so.

DYK, Circuit Judge, with whom GAJARSA, Circuit Judge, joins, dissenting from the order denying rehearing en banc.

This case presents an important question under the Hatch-Waxman Amendments, which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc (2000) and 35 U.S.C. §§ 156, 271, 282 (2000))—whether a patent holder can delay Food and Drug Administration ("FDA") approval of an application for a competing generic drug by the simple expedient of refusing

to sue for infringement. Here there is a present controversy over Teva's right to secure approval of its Abbreviated New Drug Application ("ANDA"), plainly adequate to satisfy the requirements of Article III.

The Declaratory Judgment Act, 28 U.S.C. § 2201 (2000), and the 2003 Medicare Amendments, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, Pub. L. No. 108-173, 117 Stat. 2066, 2448-69 (codified in pertinent part at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)), were designed to create a declaratory judgment remedy in circumstances permitted by Article III. The panel's holding, relying on earlier decisions of our court, that Article III bars such a remedy unless "a reasonable apprehension of *imminent* suit" exists is incorrect. *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005). I dissent from the denial of rehearing *en banc*.

I.

The plain language of the 2003 Medicare Amendments requires that in the Hatch-Waxman context the federal courts allow declaratory judgment actions to the full extent allowed by Article III. 35 U.S.C.A. § 271(e)(5) ("[C]ourts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought ... under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed."). Even if the legislative history could be read as approving our reasonable apprehension test, that history cannot overcome the plain language of the statute. So we must decide whether Article III is satisfied.

There are relatively few Supreme Court cases dealing with Article III and declaratory judgments, but the few cases that do exist provide no support for a reasonable apprehension of imminent suit requirement. The declaratory judgment statute was designed to deal with a situation in which the declaratory judgment defendant declined to bring suit, i.e., in which there was no reasonable apprehension of imminent suit. The Supreme Court case upholding the statute involved just such a situation-one in which there was no imminent risk of suit because the potential plaintiff declined to sue. *Aetna Life Ins. Co. v. Haworth,* 300 U.S. 227 (1937). In that case, the insured on several policies stopped making premium payments and made repeated claims for benefits on account of total and permanent disability. *Id.* at 237-38. Aetna refused to pay benefits because it contended that the insured was not disabled and that the policies had lapsed due to nonpayment. *Id.* at 238. The insured failed to bring suit, so Aetna filed for a declaratory judgment that the insured was not disabled and that the policies had lapsed. *Id.* at 239. The Court found that these facts gave rise to a controversy within the meaning of Article III, stating "[t]here is here a dispute between parties who face each other in an adversary proceeding.... The dispute is defined and concrete, not hypothetical or abstract.... It calls, not for an advisory opinion upon a hypothetical basis, but for an adjudication of present right upon established facts." *Id.* at 242.

Likewise, the Ninth Circuit, in a case in which the plaintiff faced a risk of liability rather than suit, has held that "[a]n action for a declaratory judgment ... is a case or controversy if the plaintiff has a real and reasonable apprehension that he will be subject to *liability,*" not suit. *Societe de Conditionnement en Aluminium v. Hunter Eng'g Co., Inc.,*

655 F.2d 938, 944 (9th Cir.1981) (emphasis added).[1] The First Circuit has even more directly addressed the issue in *Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14 (1st Cir. 2001), and adopted a view that conflicts with the panel decision in this case. There, a World Intellectual Property Organization ("WIPO") panel found Sallen to be a cybersquatter and ordered his domain name transferred to Corinthians Licenciamentos LTDA ("CL"). *Id.* at 21-22. Sallen filed suit in federal district court seeking a declaration that under United States law (which allowed a challenge to the WIPO decision) he was entitled to the domain name. *Id.* at 22. The district court dismissed the case because CL had no intent to sue Sallen under United States law. *Id.* On appeal, the First Circuit rejected CL's argument that a reasonable apprehension of suit is required to satisfy Article III:

> CL claims that a reasonable apprehension of suit is required to meet Article III's case or controversy requirement. *But this is not the only way to establish the existence of a case for purposes of Article III. The reasonable apprehension of suit doctrine exists to cabin declaratory judgment actions where the only controversy surrounds a potential, future lawsuit.* That is not this case.

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[1] That case involved a manufacturer that filed for declaratory judgment of invalidity of the defendant's patent after a potentially unauthorized person working for the defendant threatened a third party with suit if the third party purchased the plaintiff's equipment. *Id.* at 941, 944-45. The third party purchased the equipment. *Id.* at 941. A hold harmless provision in the contract between the third party and the plaintiff placed the plaintiff in reasonable apprehension of liability. *Id.* at 945.

Id. at 25 (internal citations omitted and emphasis added). The court found that United States law "provides a registrant who has lost a domain name ... with a cause of action for an injunction returning the domain name if the registrant can show that she is in compliance with" United States law. *Id.* at 26. Thus, the court found that the controversy in issue was certain and that "a certain controversy renders the 'reasonable apprehension' question irrelevant." *Id.*

In my view, the First Circuit is correct: the proper test under Article III is whether there is a present concrete controversy, and the panel here applied an incorrect test. The panel here also reached the wrong result in this case by relying on that erroneous test.

II.

Here it seems to me that there are three potential controversies:

1. There is a potential controversy over whether the ANDA filing itself was an infringement. I doubt whether this, standing alone, satisfies Article III because Pfizer seems not to care whether such an infringement occurred. *Textron Lycoming Reciprocating Engine Div., AVCO Corp. v. UAW*, 523 U.S. 653, 661 (1998) (finding no constitutional controversy where the declaratory judgment defendant had no "interest in defending the binding nature of the contract").

2. There is also a potential controversy over whether Teva should be allowed to manufacture and market the drug without incurring damages for infringement. The problem here is that Teva has not alleged that it intends to market or sell the drug at any time in the near future or that it is being prevented from doing so by the risk of infringement

damages. Instead, Teva alleges only that the filing of its ANDA constituted technical infringement; that Pfizer did not file suit within the 45-day period; that Pfizer included the '699 patent in the Orange Book; and that Pfizer tends to enforce its patents through litigation. (J.A. at 52.) Unless Teva actually is about to manufacture or sell the drug, there would seem to be no case or controversy under this theory. *Societe de Conditionnement*, 655 F.2d at 944.

3. The third potential controversy is over whether Teva's ANDA should be approved earlier than 180 days after Ivax commences marketing. In my view, there is a present and concrete controversy over Teva's right to such an approval, which satisfies the requirements of Article III. The Hatch-Waxman Amendments provide for the right to secure resolution of the controversy through a declaratory judgment.

Ivax earlier filed a paragraph IV certification regarding the '699 patent and then settled with Pfizer. Thus, Ivax will enjoy a 180-day exclusivity period beginning with the *earlier* of (1) the first day it markets its generic drug (which cannot be earlier than June 30, 2006) or (2) the date that the '699 patent is held invalid or not infringed in the decision of a court.[2] Because of the paragraph IV certification, Teva's application cannot be approved by the FDA until after Ivax's 180-day exclusivity period ends. *Teva*, 395 F.3d at 1328, 1330. In other words, the running of the exclusivity period

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[2] To be sure, Pfizer's failure to bring suit within the 45-day period specified in section 21 U.S.C. § 355(j)(5)(B)(iii) means that the approval of the ANDA will not be delayed under that section, but despite Pfizer's failure to sue, 21 U.S.C. § 355(j)(5)(B)(iv) will bar approval until 180 days after Ivax markets the drug unless there is an earlier holding of non-infringement or invalidity.

could be triggered before Ivax's first marketing date if Teva could secure a declaratory judgment of non-infringement or invalidity. Approval of Teva's ANDA would follow 180 days thereafter.

Normally, one would expect that the approval issue would be litigated between Teva and the FDA, but, as we recognized in *Minnesota Mining and Manufacturing Co. v. Barr Laboratories, Inc.*, 289 F.3d 775, 778 (Fed. Cir. 2002), Congress provided that approval would depend on the outcome of litigation between private parties (the patent owner and the potential infringer) over the questions of infringement and validity.[3] There is certainly a concrete controversy between Pfizer (and Ivax) and Teva over when Teva's ANDA should be approved. Both Pfizer and Ivax want the approval of Teva's application delayed. Teva wants to avoid delay. The question of delay turns on infringement and validity.[4] Under these circumstances, I think there is a case or controversy within the meaning of Article III, and that the questions of infringement and validity should be addressed. The panel appears to recognize the existence of a controversy, but holds that the controversy is insufficient for purposes of Article III.[5] I respectfully disagree. Under the

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[3] *See also Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003); *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

[4] While the '518 patent imposes an additional limitation on the approval of Teva's ANDA such that it could not be approved until the '518 patent expires (June 30, 2006), it is hardly premature to litigate the approval date since litigation over infringement and invalidity of the '699 patent could itself consume a significant time.

[5] The panel states that "[t]he fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from

panel's decision Teva lacks any remedy to contest the delay in its ANDA approval. I agree with Judge Mayer and Judge Gajarsa that Article III does not require such unfairness.

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whether an Article III controversy exists between Teva and Pfizer." *Teva*, 395 F.3d at 1338.

Appendix E – U.S. CONST., art. III, § 2

CONSTITUTION OF THE UNITED STATES

ARTICLE III

Section 2. The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority;--to all Cases affecting Ambassadors, other public Ministers and Consuls;--to all Cases of admiralty and maritime Jurisdiction;--to Controversies to which the United States shall be a Party;--to Controversies between two or more States;--between a State and Citizens of another State;--between Citizens of different States;--between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.

Appendix F – 21 U.S.C.A. § 355(j)(5)(C)
(West Supp. 2005)

TITLE 21 – FOOD AND DRUGS
CHAPTER 9 – FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER V – DRUGS AND DEVICES

PART A – DRUGS AND DEVICES

§ 355. New drugs

* * *

(j) Abbreviated new drug applications

* * *

(5) * * *

(C) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless--

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either--

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

Appendix G – 35 U.S.C.A. § 271(e)(5) (West Supp. 2005)

TITLE 35 – PATENTS

PART III – PATENTS AND PROTECTION OF PATENT RIGHTS

CHAPTER 28 – INFRINGEMENT OF PATENTS

§ 271. Infringement of patent

* * *

(e) * * *

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(3)

No. 05- 1006

IN THE

Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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April 12, 2006

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

QUESTION PRESENTED

Whether the court below properly determined, on the particular factual record of this declaratory-judgment action, that there was not a ripe Article III case or controversy for it to adjudicate, particularly given that the declaratory-judgment plaintiff could not yet market the potentially infringing product regardless of the outcome, and given that the plaintiff acknowledged that the declaratory-judgment defendant had no current interest in asserting its patent rights against the plaintiff.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of this Court's rules, respondent Pfizer Inc. ("Pfizer") states that it has no parent and no publicly held company owns 10% or more of its stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

TABLE OF AUTHORITIES
(Continued)

Page

Federal Statutes

TABLE OF AUTHORITIES
(Continued)

Page

Legislative History

Miscellaneous

RESPONDENT'S BRIEF IN OPPOSITION

STATEMENT OF THE CASE

In this action, petitioners Apotex Inc. and Apotex Corp. (collectively, "Apotex") seek an advisory opinion on whether a generic pharmaceutical that they may attempt to market at some point in the future, but for which they concededly will not seek FDA approval until at least July 2006, infringes a patent that they themselves allege respondent Pfizer has no present interest in asserting against Apotex. Summarily affirming the district court, the Federal Circuit properly declined the invitation to embark on such a hypothetical, speculative inquiry in light of the Article III requirement of an actual and concrete "Case[]" or "Controvers[y]." Such a routine justiciability determination, based on the specific factual circumstances of this case, and involving a statutory scheme that has since been amended to alter the analysis fundamentally in future cases, does not warrant this Court's review.

A. The Statutory Scheme Governing Expedited FDA Approval of Generic Pharmaceuticals.

1. Under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, manufacturers of both innovative and generic pharmaceuticals must follow procedures for Food and Drug Administration ("FDA") approval of a drug, which include the filing of a New Drug Application ("NDA"). *Id.* § 355(a). In the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282), (commonly referred to as the Hatch-Waxman statute), however, Congress alternatively provided for special, expedited procedures for the introduction of generic pharmaceuticals into the marketplace. Reflecting a balance between the policies of creating incentives for innovating new pharmaceuticals and allowing the prompt introduction of less-expensive generic

products into the marketplace, the expedited Hatch-Waxman procedures allow manufacturers of generic pharmaceuticals that are identical and bioequivalent to drugs previously approved by the FDA to obtain approval by filing an Abbreviated New Drug Application ("ANDA"), rather than a full NDA. 21 U.S.C. § 355(j).

The process for approval of such a tag-along ANDA application builds off of the filing of the earlier, completed NDA for a new pharmaceutical product. In conjunction with the initial NDA filing, the NDA applicant is required to provide to the FDA a list of all patents "claim[ing] the drug for which the applicant submitted the application" and "with respect to which a claim of patent infringement could reasonably be asserted." *Id.* § 355(b)(1); *see also id.* § 355(c)(2). The FDA publishes these patent listings in an appendix to the "Orange Book," *Approved Drug Products With Therapeutic Equivalence Evaluations*, *available at* http://www.fda.gov/cder/ob/default.htm (last visited Apr. 6, 2006).

An ANDA filer for FDA approval may, upon demonstrating the identity and bioequivalence of its product with the prior NDA product, rely upon the earlier drug's safety and efficacy studies. 21 U.S.C. § 355(j)(2)(A); Pet. App. 4a. Accompanying such an ANDA filing, a generic applicant must make one of four possible certifications with respect to every patent listed in the Orange Book under the NDA on which the ANDA is premised. A "paragraph I" certification states that required patent information was not filed by the NDA holder with the FDA. A "paragraph II" certification indicates that the patent in question has expired. A "paragraph III" certification states that the patent will expire on a particular date in the future, in which case the FDA cannot approve the ANDA until after that expiration date has passed. And a "paragraph IV" certification states that "the patent is invalid or will not be infringed by . . . the new drug." 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV).

Under the Hatch-Waxman Act, while steps necessary to prepare an ANDA do not constitute infringement of an Orange Book patent (even if those acts might otherwise be infringing), the actual filing of an ANDA containing a paragraph IV certification is deemed a statutory act of patent infringement. 35 U.S.C. § 271(e)(2). Moreover, an applicant's filing of an ANDA incorporating a paragraph IV certification starts a 45-day period during which the patentee may sue the ANDA applicant for this statutory infringement, and during which the ANDA applicant may not bring a declaratory-judgment action with regard to the patent that was the subject of the certification. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee sues for infringement during this period, the FDA may not approve the ANDA for thirty months, unless the lawsuit is resolved in favor of the ANDA applicant. *Id.* If the 45-day period expires without the patentee bringing suit, the FDA may approve the ANDA. *Id.*

Under the statute, the first ANDA applicant to file a paragraph IV certification receives the benefit of a 180-day exclusivity period during which the FDA may not approve any other paragraph IV ANDAs based upon the same NDA. *Id.* § 355(j)(5)(B)(iv). Under the statutory regime applicable to this case (but that has since been amended, as discussed below), the 180-day exclusivity period began to run upon the earlier of two events: The date when the ANDA product was first commercially marketed, or "the date of a decision of a court . . . holding the patent which is the subject of the certification to be invalid or not infringed." *Id.* § 355(j)(5)(B)(iv).

2. In 2003, however, Congress amended this statutory scheme in Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (the "Medicare Amendments"). The Medicare Amendments make several pertinent changes to the ANDA approval process.

Most significantly, the Medicare Amendments revise the provisions governing the 180-day exclusivity period for a first ANDA filer in all ANDAs filed after December 8, 2003. The new provisions change the statute so that, rather than have a court-decision alternative as a possible means to begin the 180-day exclusivity period, the 180-day exclusivity period begins to run only on the date of first commercial marketing. 21 U.S.C. § 355(j)(5)(B)(iv), subject to a forfeiture of the exclusivity under six circumstances: (1) if the first applicant fails timely to market the pharmaceutical; (2) if the first applicant withdraws its ANDA; (3) if the first applicant withdraws its paragraph IV certification; (4) if the first applicant fails to obtain tentative approval within specified time periods; (5) if the first applicant enters into an agreement found by the Federal Trade Commission ("FTC") or a court to violate the antitrust laws; or (6) if all patents subject to paragraph IV certifications expire. *Id.* § 355(j)(5)(D). Thus, while a court judgment of invalidity or non-infringement can factor into the exclusivity analysis, it does so only in an entirely different way from the pre-2003 regime at issue in this case — specifically, only as a subsidiary component of the "failure to market" forfeiture analysis. *Id.* § 355(j)(5)(D)(i)(I)(aa). These new criteria for starting the 180 days and the forfeiture provisions (with the exception of the collusive agreement forfeiture provision, which is not at issue here) apply only prospectively to ANDAs filed after December 8, 2003, and thus do not apply to this case. *See* Pet. App. 6a (Ivax ANDA filed in 1999), 7a (Apotex ANDA filed on October 27, 2003).

The Medicare Amendments also impose a new requirement upon ANDA applicants who file declaratory-judgment actions regarding Orange Book patents after the expiration of the 45-day period. Specifically, they require that such ANDA applicants offer confidential access to the ANDA materials to allow the patentee or NDA holder to evaluate issues pertaining to infringement. 21 U.S.C. § 355(j)(5)(C) (Supp. 2004). The Medicare Amendments

also state that, after the 45-day period, "courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought . . . under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5) (Supp. 2004).

B. The FDA's Approval of Zoloft®, The Subsequent ANDAs, And The Litigation Below

1. Pfizer manufactures and sells Zoloft®, a pharmaceutical for treating certain mood and anxiety disorders. The active ingredient in Zoloft® is sertraline hydrochloride, which acts by inhibiting the uptake of serotonin in the brain. In obtaining its NDA for this compound, Pfizer filed with the FDA a listing of patents covering Zoloft® or a method of use for Zoloft®, and the FDA published these patents in the Orange Book. Among these patents are United States Patent No. 4,356,518 (the "'518 patent"), which claims the compound sertraline hydrochloride, and United States Patent No. 5,248,699 (the "'699 patent"), which claims a particular polymorphic form of sertraline hydrochloride. Pet. App. 6a.

In 1999, the predecessor to Ivax Pharmaceuticals, Inc. ("Ivax") notified Pfizer that it had filed an ANDA seeking FDA approval to market generic sertraline hydrochloride tablets. In that ANDA, Ivax filed a paragraph III certification with regard to the '518 patent, and thus sought approval for its generic product only beginning after the expiration of that patent, which (as adjusted by the FDA for six months due to Pfizer's performance of requested pediatric studies) will not occur until June 30, 2006. Ivax also filed a paragraph IV certification (claiming invalidity or non-infringement) with regard to the '699 patent. This latter patent will not expire until September 28, 2010, but Ivax's paragraph IV certification meant Ivax was seeking approval before that second patent expires. Pet. App. 6a.

Because Ivax was the first generic manufacturer to file a paragraph IV certification, no subsequent generic applicants can obtain approval for their ANDAs until the expiration of the 180-day period provided by the statute. Under the pre-2003 Hatch-Waxman regime applicable at that time, the 180-day "exclusivity" period would commence from the earlier of Ivax's first commercial marketing of its generic product or a final, non-appealable court decision of non-infringement or invalidity with respect to the '699 patent. 21 U.S.C. § 355(j)(5)(B)(iv).

Within forty-five days after receipt of Ivax's notice, Pfizer sued Ivax, *inter alia*, for infringing the '699 patent. In May 2002, Pfizer and Ivax settled the action. In doing so, Pfizer granted Ivax a license to the '699 patent upon approval of Ivax's generic product by the FDA after the '518 patent (with pediatric exclusivity) expires on June 30, 2006. Pet. App. 6a.

On October 27, 2003, after Pfizer and Ivax had settled Pfizer's infringement lawsuit, Apotex filed an ANDA seeking approval to market generic sertraline hydrochloride tablets. Pet. App. 7a. Like Ivax, Apotex filed a paragraph III certification with respect to the '518 patent, thereby deferring its request for FDA approval until after June 30, 2006, and a paragraph IV certification with regard to the '699 patent. Pfizer did not bring suit against Apotex within forty-five days after receiving its ANDA notice, and made no threats of suit or otherwise engaged in any conduct indicating that it might sue Apotex. Consequently, the '699 patent is not an obstacle to the FDA's approval of Apotex's ANDA, which the FDA can approve immediately after the expiration of the period created by Apotex's own paragraph III certification and the expiration of the 180-day exclusivity period enjoyed by Ivax for being the first paragraph IV filer. 21 U.S.C. § 355(j)(5)(B)(ii), (iv).

2. On April 1, 2004, Apotex sued Pfizer, seeking a declaratory judgment that Apotex's proposed generic

product would not infringe the '699 patent and that claims of the '699 patent are invalid. Pet. App. 7a. Pfizer moved to dismiss the complaint for lack of subject matter jurisdiction and, on January 3, 2005, the district court granted Pfizer's motion. Pet. App. 8a.

The district court noted that there is jurisdiction under the Declaratory Judgment Act only where there is "an actual case or controversy" between the parties. Pet. App. 8a. Applying a test previously announced by the Federal Circuit for examining the presence of a constitutional case or controversy in the patent context, the district court found that there must be some "present activity which could constitute infringement," and also "an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit." Pet. App. 9a (internal quotation marks omitted). The district court rejected Apotex's argument that this "reasonable apprehension" test had been abrogated by the Medicare Amendments, Pet. App. 10a-12a, noting that the test embodies "constitutional limits of an Article III court's jurisdiction in anticipatory patent infringement declaratory judgment actions," Pet. App. 11a, and that the legislative history of the Medicare Amendments expressly indicates a congressional intent for the continued application of the test, Pet. App. 11a-12a.

Applying the "reasonable apprehension" test to this case, the district court found the infringing-activity requirement satisfied. Pet. App. 12a. The district court nonetheless found that there was no conduct by Pfizer creating any reasonable apprehension of an infringement suit. Noting that there need not be any "explicitly threatened suit" to give rise to a reasonable apprehension, the district court "consider[ed] the totality of the circumstances" in assessing that question. Pet. App. 13a.

The district court considered several factors that Apotex claimed gave rise to a reasonable apprehension of a lawsuit

against it. The district court concluded that Pfizer's mere listing of the '699 patent in the Orange Book did not create any reasonable apprehension that Pfizer would sue Apotex, noting that "[a]ccording to the plain language of the law, an Orange Book listing represents merely that, in certain circumstances, an infringement claim 'could' be asserted, but not that one will be asserted," and that it thus "does not suggest that a suit is expected or even likely." Pet. App. 13a. Moreover, the district court observed that "[a]n Orange Book listing is directed to the FDA, not any company in particular, and is submitted as a necessary element of the drug application." *Id.*

The district court also rejected Apotex's argument that Pfizer's separate decision to sue Ivax gave rise to a reasonable apprehension that it would also sue Apotex. The district court concluded that the decision whether to sue Ivax involved different strategic considerations and that, in any event, "Pfizer ha[d] not sued any of the other ANDA applicants." Pet. App. 14a.

The district court next considered Pfizer's more general "history of litigation." *Id.* The district court held that unrelated prior litigation does not create a reasonable apprehension of suit against Apotex in the absence of "ongoing litigation between the parties over a series of closely related patents involving the same technology." *Id.* The district court noted that "[c]ompanies that profit largely from research and development will frequently find themselves involved in patent infringement litigation; what creates a reasonable apprehension of suit in any given case is a relationship between that case and some prior litigation." Pet. App. 14a-15a. Because Apotex alleged no such connection with Pfizer's prior litigation, there was no ground for a reasonable apprehension of a lawsuit against Apotex here. *Id.*

Finally, the district court held that "Pfizer's refusal to acknowledge [Apotex's] non-infringement" did not create

any reasonable apprehension of suit by Pfizer. The court noted that Apotex offered no explanation for its contention that "this behavior [wa]s threatening," and found that "[a]t most, Pfizer's refusal is ambiguous; it does not affirmatively show an intent to sue." Pet. App. 15a.

Finding that the totality of the circumstances did not support any reasonable apprehension on the part of Apotex that Pfizer would sue it, the district court held that there was no jurisdiction to support Apotex's declaratory judgment action. The district court therefore granted Pfizer's motion to dismiss. *Id.*

3. After the district court's decision in this case issued, the Federal Circuit decided *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir.), Pet. App. 16a-49a, *reh'g denied*, 405 F.3d 990 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005). In *Teva*, the Federal Circuit held that a similarly situated generic manufacturer could not maintain a declaratory judgment action against Pfizer with respect to the Zoloft® patents. Like the district court in this case, the *Teva* panel majority applied the "two-part inquiry" requiring both present infringing activity and facts supporting "a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit." Pet App. 27a. Evaluating "the totality of the circumstances," Pet. App. 30a (internal quotation marks omitted), the panel majority there similarly found no case or controversy supporting Teva's declaratory-judgment action on the particular facts of that case. Teva petitioned this Court for a writ of certiorari, and this Court denied certiorari.

4. On December 12, 2005, the Federal Circuit affirmed the district court's decision in this case by a summary per curiam disposition. Pet. App. 1a.

REASONS FOR DENYING THE PETITION

The petition for a writ of certiorari should be denied. It raises no important or recurring issue warranting this Court's review; on the contrary, the decision below is entirely fact-

bound, and because of amendments to the key provisions of the statute, the concern expressed by Apotex has been abrogated by amendments to the operative ANDA regime in cases like this one. Further, the decision below is entirely consistent with this Court's decisions and the decisions of other courts. Finally, the decision below is correct on the merits; the petition's contrary argument rests on a misstatement of both the applicable law and the grounds for the decision below.

I. THE PETITION RAISES NO IMPORTANT OR RECURRING ISSUE WARRANTING THIS COURT'S REVIEW.

At the outset, it should be emphasized that the petition raises no important or recurring issue that could possibly warrant this Court's review. Under this Court's rules, the Court will expend its limited resources to review a case only where there are "compelling reasons" for doing so, including "important question[s] of federal law." Supreme Court Rule 10, 10(c). This requirement of importance of an issue is not satisfied, and a case is unsuitable for review by this Court, where the issue raised in the petition is unlikely to recur outside the case immediately under review. For example, it has been explained that, where intervening amendments to a statutory scheme diminish the likelihood of recurrence of the issue raised in a certiorari petition, an issue is not worthy of review. *See, e.g.*, John M. Harlan, *Some Aspects of the Judicial Process in the Supreme Court of the United States*, 33 AUSTRALIAN L.J. 108 (1959) (noting that review is inappropriate where the issue "is not apt to have continuing legal consequences, as where a statute which has given rise to conflicting interpretations has been repealed or amended"). Similarly, where an issue is narrowly fact-bound, it is not an appropriate candidate for review by this Court. *See, e.g., Rice v. Sioux City Mem'l Park Cemetery*, 349 U.S. 70, 74 (1955) (noting that issue should be "beyond the academic or the episodic"). For both of these reasons, the petition here does not warrant review.

First, intervening statutory amendments have fundamentally altered the relevant statutory analysis. They have replaced the procedures governing the exclusivity period in cases involving ANDAs filed after December 8, 2003.

The petition claims that the Pfizer/Ivax settlement created an incentive for Pfizer not to initiate litigation against subsequent ANDA applicants filing paragraph IV certifications, because doing so could theoretically lead to an "adverse court judgment" that, under the extant statutory regime, would cause the exclusivity period to begin running before Ivax began to market its generic pharmaceutical. The petition argues that "the failure to secure a court judgment of non-infringement or invalidity precluded Apotex" from causing the Ivax exclusivity period to start running "until *at least* 180 days after the expiration of the '518 patent." Pet. 4. Apotex asserts that the decision below "encourages brand companies to delay infringement litigation and, as a result, the market entry of much-needed affordable generic drugs." Pet. 16. This was also the issue that concerned the panel and en banc dissenters in the Federal Circuit in the *Teva* case. *See* Pet. App. 46a-47a (Mayer, J., dissenting) (claiming a "cognizable injury" based upon "brand-name firm[s] forego[ing] suing subsequent ANDA applicants" to avoid starting the 180-day period); Pet. App. 57a (Gajarsa, J., dissenting) (claiming that Pfizer "insulated itself from any judicial determination" during the 180-day period); Pet. App. 67a (Dyk, J., dissenting) (finding a controversy because "Congress provided that approval would depend on the outcome of litigation between private parties (the patent owner and the potential infringer) over the questions of infringement and validity").

That concern will not arise, however, in future cases in light of the recent Medicare Amendments. As explained above (*supra* at 4), the Medicare Amendments replaced the alternative "court decision" means of starting the 180-day period running with several exclusivity "forfeiture"

provisions, under which a court decision regarding infringement or validity plays an entirely different and substantially more limited role. Indeed, under the Medicare Amendments, an ANDA applicant must have "received tentative approval" for its generic drug in order for an adverse court judgment to enter the analysis at all. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). Therefore, a party in Apotex's position (*i.e.*, a party who like Apotex has never received tentative approval for its generic drug) could not make use of any court judgment of invalidity or non-infringement to cause forfeiture of the exclusivity period even if it obtained such a judgment. In other words, as amended, the statute no longer incorporates a simple "adverse judgment" starting point like the one at issue in this case, and the concerns asserted by the petition do not even apply to future cases of this type under the amended statute. In these circumstances, where the operative provision of the statute at issue "has been . . . amended" in a way that will radically alter the issue in future cases and prevent it from arising at all in cases like this one, certiorari review is not appropriate, because the issue raised in the petition "is not apt to have continuing legal consequences." Harlan, *supra*, 33 AUSTRALIAN L.J. at 108.

Second, even under the pre-amendments statutory regime applicable to this case, the petition raises no issue of general significance, because it arises only in a narrowly fact-intensive posture. The Federal Circuit here simply summarily affirmed the district court, and the district court did not purport to pronounce any new rule of justiciability, much less a rule of sweeping application. Rather, the court applied a longstanding test for justiciability, Pet. App. 9a-10a, and made clear that its application of that test was limited to the particular "totality of the circumstances" in the present case, Pet. App. 10a (internal quotation marks omitted); *accord id.* (considering "the full range of the defendant's conduct"); Pet. App. 13a ("consider[ing] the totality of the circumstances"). Such a decision, summarily

affirmed by the appellate court, is plainly not important enough to merit this Court's review.

Specifically, the question in this case arises in, and rests on, a quite unusual combination of independent predicate facts:

- The patentee must have two or more Orange Book patents relating to the NDA product in question.
- These patents must expire at significantly different times.
- There must be at least two prospective generic entrants into the market.
- The prospective generic entrants must file paragraph III certifications with respect to the earlier-expiring patent — thus deferring the onset of both the exclusivity period and the second entrant's attempt to market its generic product — and they must also make paragraph IV certifications with respect to the later-expiring patent.
- The patentee must settle the dispute over the later-expiring patent with the first generic entrant on terms granting it a license.
- The patentee must exhibit no conduct indicating any intention of suing the second generic entrant for infringement based upon its ANDA filing.

It was on these specific and unique facts that the district court below held that, in the "totality of the circumstances," Pet. App. 13a, no ripe case or controversy existed for adjudication. The district court expressly disclaimed reliance on any categorical rules and instead looked to the totality of the evidence to determine whether there existed a controversy of sufficient immediacy to satisfy the justiciability requirements of Article III. The Federal Circuit merely summarily affirmed that fact-bound decision. Moreover, the Federal Circuit has elsewhere clarified that "the traditional two-part test is not the only way of determining in all cases that the constitutional requirement of

an actual case or controversy has been met." Pet. App. 34a. Noting that Apotex had made a Paragraph III declaration with respect to the '518 patent, thus disclaiming any intent to market its generic product until at least June 2006, Pet. App. 7a, and that Pfizer has shown no intent to enforce its patent rights before that time, Pet. 12a, the district court here concluded that there was no current "actual controversy" between the parties, *id.*

In short, the decision below announced no broad or new principle of law and rested upon a fact-bound evaluation of the unusual record in this case. Accordingly, the decision below does not rise "beyond the academic or the episodic," and does not warrant consuming this Court's limited resources to review. *Rice*, 349 U.S. at 74.

II. THE DECISION BELOW IS CONSISTENT WITH THIS COURT'S DECISIONS AND CREATES NO SPLIT AMONG THE CIRCUITS.

Nor is review warranted to resolve any conflict between the decision below and either the decisions of this Court or the decisions of other courts of appeals. The petition errs in suggesting that any such conflict exists. Pet. 8-13.

1. The district court's reliance on and application of the "reasonable apprehension" standard, and the Federal Circuit's summary affirmance of that decision, are fully supported by this Court's cases. That standard distinguishes ripe, justiciable declaratory-judgment actions from those that are not ripe and immediate.

a. As this Court has long held, in order to present a ripe, justiciable controversy, a declaratory judgment action "must be definite and concrete, touching the legal relations of parties having adverse legal interests," not merely "of a hypothetical or abstract character." *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). Specifically, the Court has held that a declaratory-judgment dispute must have "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Md. Cas. Co. v. Pac.*

Coal & Oil Co., 312 U.S. 270, 273 (1941); *accord, e.g., Lake Carriers' Ass'n v. MacMullan*, 406 U.S. 498, 508 (1972).

Applying that standard, this Court has routinely held nonjusticiable declaratory-judgment actions that fail the requirements of ripeness and immediacy. For example, in *Texas v. United States*, 523 U.S. 296 (1998), the Court unanimously rejected as unripe a declaratory judgment action brought by a State to determine whether a potential future action authorized by a State statute under certain circumstances that were not yet present would trigger the preclearance provisions of the Voting Rights Act. *See id.* at 300 ("A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." (internal quotation marks omitted)). And, in *Textron Lycoming Reciprocating Engine Division v. United Automobile, Aerospace & Agricultural Implement Workers of America*, 523 U.S. 653 (1998), the Court found no Article III controversy sufficiently ripe to support a union's declaratory-judgment action to determine the validity of a collective-bargaining agreement, because there was "no indication that [the employer] had any interest in defending the binding nature of the contract." *Id.* at 661. *See also Ashcroft v. Mattis*, 431 U.S. 171, 172-73 & n.2 (1977) (per curiam) (finding no "present, live controversy" supporting a declaratory judgment based upon "speculation" about potential future legal adversity); *Laird v. Tatum*, 408 U.S. 1, 10 (1972) (rejecting justiciability of declaratory judgment action based upon allegation "that the exercise of his First Amendment rights is being chilled by the mere existence, without more, of a governmental investigative and data-gathering activity").

The immediacy requirement has led to more specific ripeness tests in particular contexts. Of particular importance here, for example, the Court has made it clear that constitutional challenges to statutes fail to satisfy the case or controversy requirement unless there is an imminent threat of prosecution under the statue. Thus, in *Boyle v.*

Landry, 401 U.S. 77 (1971), the Court rejected constitutional challenges to particular State laws on particular facts because there was no "specific threat by any officer or official . . . to arrest or prosecute" the plaintiffs. *Id.* at 81. In the absence of any such concrete threat, any judicial resolution would involve improper "speculation about the future." *Id. See also Elec. Bond & Share Co. v. Secs. & Exch. Comm'n*, 303 U.S. 419, 443 (1938) (refusing to offer "an advisory decree upon a hypothetical state of facts" in a declaratory challenge to provisions of a regulatory statute not under threat of actual prosecution); 10B Charles Alan Wright, *et al.*, *Federal Practice and Procedure* § 2757, at 477-84 (3d ed. 1998) (noting that "courts have declined to hear cases seeking a declaratory judgment on the constitutionality of a particular statute or ordinance when plaintiff has not shown that there is any immediate threat that the statute will be enforced against him").

The Federal Circuit's "reasonable apprehension" test is a well-established analogue to the imminent threat of prosecution standard. It applies that standard, and more generally adapts the immediacy requirement, to the context of declaratory judgments over patent infringement and validity issues. Paralleling the requirement of an actual threat of prosecution in the statutory context, the "reasonable apprehension" test requires some threat or conduct by the patentee "which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit." Pet. App. 27a. In short, the "reasonable apprehension" test flows naturally from this Court's cases, and plainly is not in conflict with them.

b. The petition claims that the decision below conflicts with several cases discussing the requirements for Article III standing. Pet. 9 (citing *Bennett v. Spear*, 520 U.S. 154 (1997), and *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83 (1998)). But both of these cases address only the requirements for standing, because it was the only justiciability requirement at issue in them. *See Bennett*, 520

U.S. at 160-61; *Steel Co.*, 523 U.S. at 88-89. Nothing in these cases purports to displace this Court's other cases holding that, in addition to standing, ripeness is also a prerequisite for justiciability. *See, e.g.*, *Allen v. Wright*, 468 U.S. 737, 750 (1984) (noting that justiciability involves "not only standing but mootness, ripeness, political question, and the like" (internal quotation marks omitted)); *Warth v. Seldin*, 422 U.S. 490, 499 n.10 (1975) (discussing relationships among standing, ripeness, and mootness requirements). Indeed, *Steel Co.* noted that the standing requirements that it discussed comprised only "part of" the constitutional test for justiciability. 523 U.S. at 102.

Apotex asserts that *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83 (1993), is somehow inconsistent with the decision below. But *Cardinal Chemical Co.* involved the unrelated issue whether an appellate determination of noninfringement renders moot a declaratory judgment counterclaim challenging the patent's validity. *See id.* at 89, 95. There was no question in that case that the declaratory judgment was ripe for adjudication in the first instance, because it followed an actual infringement lawsuit by the patent holder. *See id.* at 96 ("In this case, . . . it is perfectly clear that the District Court had jurisdiction to entertain Cardinal's counterclaim for a declaratory judgment of invalidity" because it "ha[d] actually been charged with infringement of the patent."). The dictum in that case regarding the scope of declaratory judgment jurisdiction in the first instance merely noted that "a party may satisfy" the case or controversy requirement "even if the patentee has not filed an infringement action," *id.* at 95, but nonetheless noted the "requirement for jurisdiction under the Act . . . that the conflict be real and immediate, *i.e.*, that there be a true and actual 'controversy,'" *id.* at 96 (internal quotation marks omitted). This is consistent with the "reasonable apprehension" test, which does not require an actual lawsuit, but merely some conduct creating a reasonable likelihood that one may be imminently brought.

Apotex's discussion of *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227 (1937), exhibits the same confusion on Apotex's part. Apotex suggests that *Aetna Life* conflicts with the "reasonable apprehension" standard because the declaratory judgment defendant in that case had not filed suit, yet jurisdiction was upheld. Pet. 10-11. Yet the "reasonable apprehension" test applied below does not require an actual lawsuit, but rather merely a reasonable apprehension of one being imminently filed. And the declaratory judgment defendant in *Aetna Life*, an insured, had taken concrete steps to put the plaintiff insurance company on reasonable notice of an adverse legal position, thus creating a reasonable apprehension of suit. *See* 300 U.S. at 237. Indeed, the insured had not only affirmatively "claimed the disability benefits" in question, but had "repeatedly renewed" those claims. *Id.* And, in finding a controversy that was ripe for resolution, the Court relied on those facts, finding that the dispute was not "hypothetical or abstract," but was ripe and immediate, *id.* at 240, because, "[p]rior to this suit, the parties had taken adverse positions with respect to their existing obligations," *id.* at 242. Indeed, *Aetna Life Insurance* is cited in this Court's cases for its recognition and application of the immediacy requirement. *See, e.g., Md. Cas. Co.*, 312 U.S. at 273.

2. The decision below is also entirely consistent with the law in other circuits. In a footnote, the petition claims that there are "[c]onflicts between the Federal Circuit's decisions and those of other circuits." Pet. 13-14 n.6. In fact, both of the cases cited by Apotex expressly adopt the very same "reasonable apprehension" test as did the decision below, and thus merely reinforce the correctness and settled nature of that test.

United Christian Scientists v. Christian Science Board of Directors, 829 F.2d 1152 (D.C. Cir. 1987), *see* Pet. 14 n.6, involved a declaratory judgment action challenging the constitutionality of a law granting a copyright extension. 829 F.2d at 1154. The panel addressed the issue of subject-

matter jurisdiction in a footnote, and held that "[t]he 'actual controversy' requirement 'is satisfied when a defendant's conduct has created on the part of the declaratory plaintiff a reasonable apprehension that it will face an infringement suit if it commences or continues the activity in question,'" and where there has been infringing activity. *Id.* at 1158 n.25 (quoting *Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 883 (Fed. Cir. 1985)) (internal quotation marks omitted). Like the decision below, the panel noted that, while "the declaratory defendant need not actually charge infringement" to satisfy this standard, the declaratory judgment plaintiff "must establish that his apprehension of infringement charges is reasonable and objectively manifested in light of the totality of the circumstances." *Id.* The panel found that the totality of the circumstances in the *United Christian Scientists* case constituted "an implied threat" of litigation sufficient to support jurisdiction over the declaratory judgment action. *Id.* In short, the D.C. Circuit expressly agreed with and applied the "reasonable apprehension" standard used in this case.

Similarly, *Sherwood Medical Industries, Inc. v. Deknatel, Inc.*, 512 F.2d 724 (8th Cir. 1975), held that jurisdiction over a declaratory judgment action must be supported by "conduct or [a] course of action on the part of the patentee which would lead a reasonable man to fear that he or his customers face an infringement suit or the threat of one if he continues or commences the activity in question." *Id.* at 728. The panel found that the declaratory judgment plaintiff in *Sherwood Medical* "ha[d] a 'reasonable apprehension' that it would be faced with an infringement suit if it commenced marketing its chest drainage device," in light of various circumstances, including a letter from the patent holder's attorney and statements made by "a high ranking employee" of the patent holder suggesting that it might sue. *Id.* Once again, the Eighth Circuit used the very same standard for subject-matter jurisdiction as did the decision below.

III. THE PETITION IS WRONG ON THE MERITS OF THE QUESTION PRESENTED.

Finally, the decision below is correct on the merits. The petition is wrong in arguing to the contrary; and the errors in its arguments further show why certiorari review is inappropriate in this case.

1. The district court correctly ruled that there is no present case or controversy between the parties that would support Apotex's declaratory-judgment action. In order for a constitutionally cognizable claim or controversy to exist, there must be an actual dispute between the parties that is both "immedia[te] and real[]." *Md. Cas. Co.*, 312 U.S. at 273. In this case, Apotex concedes the facts showing that there is no current dispute between the parties regarding the subject of its declaratory-judgment action, namely the validity or infringement of the '699 patent.

Significantly, no conceivable controversy over the '699 patent can occur for some time into the future, in light of Apotex's paragraph III certification with respect to the '518 patent — which Apotex acknowledges precludes it from obtaining approval for, or marketing, its generic product until after June 2006 without regard to the '699 patent — and Ivax's statutory exclusivity period following it. Apotex has not represented that Pfizer will choose to assert any patent claims against it based upon any generic product that Apotex may one day attempt to market. Indeed, Apotex concedes that Pfizer declined to bring any infringement action of its own in response to Apotex's ANDA filing, Pet. 4, and Apotex itself alleges that Pfizer will not commence such an infringement action, if any, until at least after Ivax's exclusivity period has run. These are precisely the circumstances constituting hypothetical future controversies that this Court has rejected as inadequate to support a justiciable declaratory-judgment action. *See, e.g., id.*

As Judge Dyk indicated in his dissent from the Federal Circuit's denial of *en banc* review in the similar *Teva* case,

Pet. App. 65a, there is no case or controversy where the declaratory-judgment defendant has expressed no desire to enforce the right in question. *See Textron*, 523 U.S. at 661 (finding no case or controversy where there was "no indication that Textron had any interest in defending the binding nature of the contract" whose validity was the subject of the declaratory-judgment action). Here, as in *Teva*, Apotex itself claims that, far from having any desire to assert its patent rights against Apotex, Pfizer has an incentive "to *delay* infringement litigation," at least until some future time when the Ivax exclusivity period has ended. Pet. 16 (emphasis added). But, as Judge Dyk also recognized regarding the similarly situated generic manufacturer in *Teva*, Pet. App. 66a, it is not yet the case that Apotex "actually is about to manufacture or sell the drug"; and it is even more speculative whether, if Apotex did, Pfizer would at that point commence any infringement action. Therefore, under this Court's cases, there is no present controversy over the subject of Apotex's action.

2. No doubt in light of these facts, the petition does not primarily argue that there is any present dispute over the infringement or validity of the '699 patent. Instead, Apotex alleges that it "is injured," Pet. 11, by the (pre-Medicare Amendments) statutory scheme governing the ANDA process. Its alleged injury has nothing to do with a fear of suit by, or liability to, Pfizer, but rather rests on the claim that "the failure to secure a court judgment prohibits *the federal government* from approving" Apotex's product, Pet. i (emphasis added), and therefore that Apotex might be "prevent[ed from] marketing . . . a generic equivalent to Zoloft®," Pet. 4. Similarly, the Federal Circuit dissenters in the *Teva* case relied upon this same theory of an injury stemming from a delay in FDA approval under the Hatch-Waxman regime. Pet. App. 46a-47a (Mayer, J., dissenting), 56a-58a (Gajarsa, J., dissenting), 66a-68a (Dyk, J., dissenting). Indeed, the Federal Trade Commission, in a Federal Circuit *amicus* brief in *Teva*, acknowledged that the

panel's application of the "reasonable apprehension" standard would have been appropriate "in a classic patent declaratory judgment suit," FTC *Teva* Br., *available at* http://www.ftc.gov/ogc/briefs/teva_v_pfizer.pdf, at 17 (last visited Apr. 6, 2006) (internal quotation marks omitted), but urged the Federal Circuit to create a special exception in the Hatch-Waxman context owing to this alleged injury from a delay in being able to obtain FDA approval, *see id.* at 18. These arguments are seriously confused and profoundly wrong.

A declaratory-judgment action allows the natural defendant in a dispute to initiate litigation over an injury that would have been the subject of the declaratory-judgment *defendant's* lawsuit that it has not yet initiated, but that is hanging over the head of the declaratory-judgment plaintiff. *See, e.g., Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 504 (1959) (holding that the Declaratory Judgment Act "allow[s] prospective defendants to sue to establish their nonliability"). The injury question in a declaratory-judgment action is whether there is a sufficient and immediate harm to the declaratory-judgment *defendant* to support its assertion of a cognizable claim against the declaratory-judgment plaintiff to allow the plaintiff to file an anticipatory action to declare its liability or nonliability for that injury. *See, e.g., Md. Cas. Co.*, 312 U.S. at 273 ("It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed; the inquiry is the same in either case.").

For this reason, Apotex's reference to the injury that *it* allegedly suffers from a potential delay in starting Ivax's exclusivity period under the Hatch-Waxman procedures is ill-conceived. Pfizer is the declaratory-judgment defendant, and Apotex is the declaratory-judgment plaintiff. Thus, for purposes of determining whether a declaratory-judgment action about the '699 patent is justiciable, the question is whether *Pfizer* has suffered a legally cognizable injury that is ripe for adjudication, not whether Apotex has suffered a

legally cognizable injury that is ripe for adjudication. Any such injury to Apotex could perhaps conceivably supply standing for it to bring a direct, non-declaratory lawsuit involving proper parties premised on that injury; but it does not make ripe any declaratory-judgment controversy over the '699 patent, which Apotex itself alleges that Pfizer has no current interest in asserting against it. Apotex's alleged injury would not involve "the same" one as a direct patent-infringement claim brought by Pfizer, and thus cannot support declaratory-judgment jurisdiction for this case (as opposed to some other case involving the defendant who allegedly caused *that* injury). *Md. Cas. Co.*, 312 U.S. at 273.

This conceptual defect is presented particularly starkly in this case. Apotex's claimed injury is not only different from the fear of being called to account for Pfizer's claim of patent infringement, but it is the precise opposite of such a claim. Apotex's claimed injury results from its claim that Pfizer will *not* assert any patent rights against it for some time, if at all, and that Apotex will suffer a competitive disadvantage to Ivax as a consequence. Apotex thus in effect claims an injury from the very *lack* of any controversy over the '699 patent. Simply to expose the claim is to show why no declaratory-judgment action against Pfizer (as opposed to a lawsuit against Ivax or the FDA) is proper. Thus, this case is at the opposite extreme from a declaratory-judgment case like *MedImmune, Inc. v. Genentech, Inc.*, No. 05-608, 126 S. Ct. 1329 (Feb. 21, 2006), in which this Court has granted certiorari to consider the entirely distinct issue of whether a patent licensee must breach a license before commencing a declaratory-judgment action about it. As the Federal Circuit observed in that case, "[l]icensor and licensee always have adverse legal interests," 427 F.3d 958, 964 (Fed. Cir. 2005) (internal quotation marks omitted), and the declaratory-judgment plaintiff in that case relied upon the risk that the licensor would sue it if it stopped payment on the license. *See id.* at 963. The issues relating to genuinely adverse parties to a license are wholly unrelated to those in this case,

where the subject of the lawsuit is admittedly entirely different from the injury alleged to support it — and relates to a statutory scheme that has since been amended in key respects (and is not at issue in *MedImmune*).

It may be assumed, as Apotex alleges, that the 180-day exclusivity period for Ivax places Apotex at a competitive disadvantage. It may even be assumed, as Judge Dyk assumed (albeit perhaps incorrectly) in his *Teva* dissent, that, under the statute, Apotex cannot bring suit directly against either Ivax or the FDA to attempt to eliminate or shorten this competitive disadvantage. The constitutionally appropriate response to this competitive disadvantage is *not* to treat an unripe, hypothetical claim of infringement by Pfizer as nonetheless justiciable. Rather, as the *Teva* panel majority recognized, Pet. App. 40a, the constitutionally appropriate response to this situation is to deny justiciability and to allow Congress to amend the statute to address any perceived deficiencies in the legal regime that it created. And that, of course, is precisely what Congress did in the 2003 Medicare Amendments — which is just another reason why certiorari review of the decision below is plainly unwise and unnecessary.

3. Contrary to the claims of the petition, Pet. 14-19, the decision below is also entirely consistent with the intent of Congress in crafting the prospective provisions of the Medicare Amendments, and particularly the provision stating that declaratory-judgment actions may be brought outside the initial 45-day period for the patentee to sue. 35 U.S.C. § 271(e)(5). By its express language, that provision does not attempt to confer any new jurisdiction beyond that already available under the Declaratory Judgment Act, and contemplates that any such jurisdiction must be "consistent with the Constitution," *id.*, including the constitutional requirement that a real, immediate, and ripe case or controversy must exist.

Indeed, Congress left no doubt about whether it expected the "reasonable apprehension" test would survive the amendment. The Conference Committee Report repeatedly states that the drafters "d[id] not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction." H.R. Conf. Rep. No. 108-391, at 836 (2003), *reprinted in* 2004 U.S.C.C.A.N. 1808, 2187 (citation omitted). *See also id.* (stating expectation that courts would "apply the 'reasonable apprehension test'"); 149 Cong. Rec. S15,533-02, S15,567 (daily ed. Nov. 22, 2003) (statement of Sen. Hatch) (noting that "the settled case law of the 'reasonable apprehension' test remains undisturbed"). The report also observes that "[i]n any given case, . . . a court may or may not find a reasonable apprehension of suit." H.R. Conf. Rep. No. 108-391, at 836, *reprinted in* 2004 U.S.C.C.A.N. at 2187.

The petition attempts to dismiss all of this legislative history in a conclusory footnote, Pet. 18 n.12, stating that it "obviously cannot be reconciled with the statutory text." Pet. 11 n.5. As shown above, the legislative history merely reinforces the plain meaning of the statutory text, and disproves Apotex's claims that the plain meaning is somehow contrary to the legislative intent.

Finally, a provision that would have purported to confer automatic jurisdiction such as Apotex urges here was proposed in the Senate, but was ultimately rejected. In the Senate bill, a patentee's failure to sue within 45 days of receipt of a paragraph IV notice would have "establish[ed] an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in . . . any action . . . for a declaratory judgment that any patent that is the subject of the certification is invalid or not infringed." Prescription Drug and Medicare Improvement Act of 2003, S. 1, 108th Cong., § 702(c) (2003). The proposal was rejected in conference after Senator Hatch, co-sponsor of the

Hatch-Waxman legislation, expressed concern about the constitutionality of authorizing "subject matter jurisdiction for a declaratory judgment based on the failure to bring a suit . . . particularly in light of [the] manner in which the U.S. Courts of Appeals, including the Federal Circuit, have developed and applied the 'reasonable apprehension' test." 149 Cong. Rec. S8686, S8691 (daily ed. June 26, 2003) (statement of Sen. Hatch).

In short, through the plain language of the Medicare Amendments, through the express articulation of the conference report, and through a rejection of a more expansive proposal, Congress endorsed the "reasonable apprehension" test and expected the courts to continue to apply it in cases under the amended statute. The petition has no proper basis for suggesting otherwise.

CONCLUSION

The petition for a writ of certiorari should be denied.

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April 12, 2006

No. 05- 1006

IN THE

Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

SUPPLEMENTAL BRIEF FOR RESPONDENT

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of this Court's rules, respondent Pfizer Inc. ("Pfizer") states that it has no parent and no publicly held company owns 10% or more of its stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

Federal Statutes

SUPPLEMENTAL BRIEF FOR RESPONDENT

Pfizer submits this supplemental brief pursuant to Rule 16.8 of this Court's rules to inform the Court of factual developments occurring after Pfizer filed its opposition that have rendered the case moot.

STATEMENT OF THE CASE

Two intervening developments have eliminated any arguable present or future controversy between the parties about the patent that is the subject of this declaratory judgment action.

First, on August 10, 2006, Pfizer sent to counsel for Apotex an unconditional covenant not to sue Apotex with respect to that patent, United States Patent No. 5,248,699 (the "'699 patent"). *See* Addendum at 1a-2a. This covenant ensures that Apotex will never face any risk of a lawsuit by Pfizer under the subject patent.

Second, on August 14, 2006, Teva Pharmaceutical Industries Ltd. ("Teva"), the successor to Ivax Pharmaceuticals, Inc., publicly announced that it had begun marketing its generic version of Zoloft®. *See* Addendum at 3a-5a. Under the statutory regime applicable to this case (which has been amended for future cases, *see* Opp. at 3-5), Teva's marketing started the 180-day exclusivity period that Apotex sought to trigger with a hypothetical court judgment in its favor. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Therefore, any future court judgment regarding the '699 patent would no longer have any effect on the exclusivity period.

Because of these developments, counsel for Pfizer suggested to Apotex that the case is moot and requested that Apotex withdraw its petition for a writ of certiorari. However, on August 18, 2006, counsel for Apotex replied that it did not consider the case moot and that it would not withdraw the petition. Apotex did not explain how any issue

in the case could survive the intervening developments described above.

SUPPLEMENTAL REASONS FOR DENYING THE PETITION

A case becomes moot if the plaintiff "no longer has a legally cognizable interest in the outcome." *City News & Novelty, Inc. v. City of Waukesha*, 531 U.S. 278, 283 (2001) (internal quotation marks omitted). Thus, where a complaining party has "received the full relief he requested," *Clayton v. Int'l Union, United Auto., Aero., & Agric. Implement Workers of Am.*, 451 U.S. 679, 692 (1981), there remains no constitutional case or controversy between the parties and the action becomes moot. In particular, a declaratory judgment action becomes moot when the relief requested by the plaintiff has become unnecessary because the underlying alleged injury has been removed or the relief sought from the court has already been provided. *See, e.g.*, *Golden v. Zwickler*, 394 U.S. 103, 109-10 (1969) (declaratory judgment action to adjudicate right to distribute literature opposing Congressman moot where Congressman became a judge); *Taylor v. McElroy*, 360 U.S. 709, 710-11 (1959) (per curiam) (action seeking declaratory and injunctive relief based on denial of security clearance mooted by issuance of clearance and guarantee against revocation based on subject grounds).

In this case, Apotex seeks to adjudicate whether a potential future generic drug contemplated by Apotex would infringe the '699 patent, and whether the '699 patent is valid. In light of Pfizer's covenant not to sue Apotex with respect to the '699 patent, Apotex no longer faces any risk of a lawsuit under that patent, thus eliminating any interest Apotex might have had in adjudicating either the patent's infringement or its validity. The covenant not to sue effectively gives Apotex the full relief that a court could provide in this action. Indeed, Apotex argued below that there was a cognizable dispute because Pfizer had *not* "given

Apotex a covenant not to sue." Brief for Plaintiffs-Appellants Apotex Inc. and Apotex Corp., No. 05-1199, at 19 (Fed. Cir. Mar. 22, 2005); *see also id.* at 41-42. Now that Apotex has received such a covenant, there is no potential present or future adversity between the parties about the '699 patent. The case is thus legally moot.

Apotex has argued that, apart from any threat of suit by Pfizer on the '699 patent, Apotex is harmed by its inability to use a hypothetical future court judgment in its favor to start the 180-day statutory exclusivity period in favor of Teva. As Pfizer explained in its opposition (at 21-24), this purported collateral "injury" could not properly sustain a declaratory judgment action against Pfizer regarding the '699 patent. But, in any event, any such issue is now also moot due to the intervening fact of Teva's marketing its generic product. Under the pre-amendments statutory regime applicable to this case, the exclusivity clock begins running with the earlier of Teva's marketing or a court judgment of non-infringement or invalidity. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Now that Teva's marketing has already started the 180-day clock, no court judgment could have any effect on the exclusivity analysis, even if Apotex could obtain such a judgment before the 180-day period ended. Thus, even Apotex's non-justiciable interest in this case is legally moot.

Nor does this case fall within the exception to the mootness doctrine for issues that are capable of repetition yet evading review. That doctrine "applies only in exceptional situations." *City of Los Angeles v. Lyons*, 461 U.S. 95, 109 (1983). Specifically, in order for that narrow exception to apply, (1) the challenged action must be too short in duration "to be fully litigated prior to cessation or expiration," and (2) there must be a reasonable expectation that the same plaintiff will face the same issue again in the future. *Spencer v. Kemna*, 523 U.S. 1, 17 (1998). Neither of these requirements is even arguably satisfied here.

As to the durational requirement, this is not a case where there is some intrinsic reason why any future litigation over the same issue would be too short to allow judicial resolution of the issue, for example, because the underlying issue involves an inherently transitory condition, *see Roe v. Wade*, 410 U.S. 113 (1973), or because disputes of the kind at issue "typically are resolved quickly by executive or legislative action," *Burlington N. R.R. Co. v. B'hood of Maintenance of Way Employes*, 481 U.S. 429, 436 n.4 (1987). To the contrary, when Pfizer litigated the very same legal issue involving the same patent at issue here against another generic drug manufacturer, the case proceeded through final judgment, appeal, and Supreme Court review without the case becoming moot. *See Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir.), *reh'g denied*, 405 F.3d 990 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005).

Nor is Apotex likely to face the same issue again in the future, *Spencer*, 523 U.S. at 17. In the first place, as shown in Pfizer's opposition (at 11-14), there is little likelihood that the patent issues to be adjudicated in this declaratory judgment action would recur, both because the statutory scheme has been fundamentally altered for future cases, and because the issues here are highly fact-bound. Moreover, given Pfizer's covenant not to sue, there is no chance of recurrence, because the issues in this case are whether an Apotex product would infringe the '699 patent, and whether that patent is valid. Now that Apotex has received an enforceable guarantee that it will never be sued on that patent, Apotex will assuredly never need to litigate those issues again in the future. *See, e.g., Deakins v. Monaghan*, 484 U.S. 193, 199-201 (1988) (respondent's commitment not to seek equitable relief precluded its reassertion and rendered the capable of repetition yet evading review exception unavailable). More generally, Apotex could not satisfy this prong of the "capable of repetition yet evading review" exception even with respect to the broader question of whether similar disputes involving different patents might

recur in the future. Patent rights are valuable and patentees do not lightly or frequently relinquish them. Thus, there is little reason to assume that Apotex will again face a situation where its desire to litigate validity and/or infringement issues will be mooted by issuance of a covenant not to sue, as innovators will not usually be willing to abandon valuable intellectual property rights.

As an illustration, in this case, the subject patent is not even the primary patent protecting Zoloft®; the subject patent merely claims one particular form of the active ingredient in Zoloft®. Thus, Pfizer was not willing to waive its rights on the '699 patent in the earlier *Teva* litigation, because the principal patent claiming that active ingredient was still viable and enforceable. However, once the basic patent expired, Ivax's ANDA was approved immediately, and the value of the '699 patent was transferred to Ivax by virtue of its license from Pfizer; after that, no lawsuit on the '699 patent could operate to maintain exclusivity for the Zoloft® brand. Once Teva's generic product entered the market, Pfizer lost any commercial interest in asserting the '699 patent. In short, Pfizer's decision to grant a covenant not to sue in this case is no basis for Apotex contending that it will be denied the opportunity in other cases to litigate validity and infringement issues.

In sum, the fact that Pfizer has given Apotex a covenant not to sue moots the case. Even a mere voluntary cessation of conduct can moot a case. *See, e.g.*, *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979). While the potential for reinstitution of conduct voluntarily ceased sometimes keeps a case alive, an enforceable relinquishment of rights fully moots a dispute. *See, e.g.*, *Deakins*, 484 U.S. at 200-01. And, under this Court's cases, the mere "potential for manipulation" by repeating mootness-inducing conduct in future cases does not itself justify application of the exception. *Id.* at 200-01 & n.5 (potential reassertion in future case insufficient to avoid mootness). Indeed, the significant financial costs of forfeiting valuable patent rights

prevent any realistic possibility that covenants not to sue could be used as a systematic tool to manipulate the jurisdiction of the federal courts.

CONCLUSION

The petition for a writ of certiorari should be denied, or dismissed as moot.

Respectfully submitted,

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September 1, 2006

APPENDIX

No. 05- 1006

IN THE

Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

COVENANT

WHEREAS, Pfizer Inc. ("Pfizer") owns all right, title and interest in and to United States Patent No. 5,248,699 ("the '699 patent"); and

WHEREAS Apotex Inc. and Apotex Corp. (together "Apotex") filed in the United States District Court for the Southern District of New York a civil action against Pfizer, Civil Action No. 04-CV-02539 (DC), in which Apotex sought a declaratory judgment that, inter alia, "the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic sertraline hydrochloride drug produce, that is the subject of ANDA No. 76-882, does not and will not infringe . . . any valid or enforceable claim of the '699 patent";

WHEREAS the civil action brought by Apotex was dismissed upon motion by Pfizer, and the dismissal of

Apotex's civil action was affirmed upon appeal to the United States Court of Appeals for the Federal Circuit;

WHEREAS Pfizer Inc., to avoid still further litigation with Apotex, will grant Apotex a covenant not to sue with respect to the '699 patent;

NOW THEREFORE, Pfizer hereby states as follows:

1. Pfizer unconditionally agrees, promises and covenants that Pfizer will not sue or otherwise enforce the '699 patent against Apotex in connection with the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic sertraline hydrochloride drug product, that is the subject of ANDA No. 76-882.

2. This covenant shall not be construed as a license, implied or otherwise, to any claim of any other patent, or any other claim or patent owned by or licensed to Pfizer, now or in the future. This covenant does not constitute an admission by Pfizer that the claims of the '699 patent are invalid or not infringed by Apotex in connection with the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic sertraline hydrochloride drug product, that is the subject of ANDA No. 76-882.

3. This covenant shall be binding upon and inure to the benefit of the parties and their respective successors-in-interest.

Dated: August 9, 2006 By: [signed]
Peter C. Richardson
Senior Vice President and
Associate General Counsel
Pfizer Inc.

Press Release

Teva Announces Launch of Generic Zoloft®

Jerusalem, Israel, August 14, 2006 — Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that it has begun the sale of its generic version of Pfizer's Zoloft® (Sertraline) Tablets, 25 mg, 50 mg, and 100 mg in the United States. As the first company to file an ANDA containing a paragraph IV certification for this product, Teva has been awarded a 180-day period of marketing exclusivity.

Teva's AB-rated Sertraline Tablets are indicated for treatment of major depressive disorder. Annual brand product sales in the U.S. were approximately $3.1 billion for the twelve months ended June 2006, based on IMS data.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the leading generic pharmaceutical company. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients, as well as animal health pharmaceutical products. Over 80% of Teva's sales are in North America and Europe.

Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995: This release contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause Teva's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks

relating to Teva's ability to rapidly integrate Ivax Corporation's operations and achieve expected synergies, Teva's ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic products, the impact of competition from brand-name companies that sell or license their own brand products under generic trade dress and at generic prices (so called "authorized generics") or seek to delay the introduction of generic product, the impact of consolidation of our distributors and customers, regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding litigation, including that relating to the generic versions of Allegra®, Neurontin®, Oxycontin® and Zithromax®, the effects of competition on Copaxone® sales, including as a result of the expected reintroduction of Tysabri® into the market, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, Teva's ability to successfully identify, consummate and integrate acquisitions, potential exposure to product liability claims, dependence on patent and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism or major hostilities, environmental risks, fluctuations in currency, exchange and interest rates, operating results and other factors that are discussed in Teva's Annual Report on Form 20-F and its other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

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No. 05-1006

In the Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

SUPPLEMENTAL BRIEF FOR PETITIONERS

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September 19, 2006

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CORPORATE DISCLOSURE STATEMENT

The parent company of Apotex Inc. is Apotex Pharmaceutical Holdings, Inc. The parent company of Apotex Corp. is Apotex Holdings, Inc. There is no publicly-held corporation that owns 10% or more of either Apotex Inc. or Apotex Corp.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

Federal Statutes

SUPPLEMENTAL BRIEF FOR PETITIONERS

Apotex submits this supplemental brief, pursuant to Rule 15.8 of this Court's rules, in response to Pfizer's supplemental brief and suggestion of mootness.

STATEMENT OF THE CASE

The "factual developments" discussed in Pfizer's supplemental brief do not render this appeal moot or any less worthy of this Court's review. On the contrary, the underlying dispute between Apotex and Pfizer—regarding the improper application of the Federal Circuit's so-called "reasonable apprehension" test to the Hatch-Waxman declaratory judgment mechanism—remains very much a live controversy of critical importance to Apotex, the generic pharmaceutical industry, and the public that relies upon that industry to bring affordable medicines to market.

Apotex brought this declaratory judgment suit to alleviate the enormous harm that it was suffering, and continues to suffer, by virtue of Pfizer's conduct and refusal to resolve a legitimate patent dispute. Apotex's harm includes its inability to obtain approval of its non-infringing generic product and compete in the market *and* the debilitating uncertainty associated with potentially huge infringement damages. After two-plus years of litigation, Pfizer now seeks to moot this case with an unsolicited covenant not to sue. The Court should reject Pfizer's transparent attempt to manipulate this Court's jurisdiction and insulate the favorable decision below from review.

First, Apotex retains a cognizable interest in the outcome of this case notwithstanding Pfizer's strategically-timed covenant and Teva's generic product launch. The covenant does nothing to alleviate the harm caused by Apotex's inability obtain the approval needed to enter the market, as it is entitled to do. Nor does Pfizer's carefully-

worded covenant apply to Apotex's suppliers and customers, without whom there is no market for Apotex's product.

Second, even if Apotex's product is approved 180 days after Teva's launch, Pfizer's voluntary conduct does not moot this appeal because Pfizer cannot satisfy its formidable burden of showing that its conduct will not recur. This very same dispute already has occurred between Apotex and Pfizer with respect to the drug Accupril®. There, too, Pfizer attempted to manipulate the reviewing court's jurisdiction and insulate a favorable decision from review by providing Apotex with an unsolicited covenant on the eve of argument before the Federal Circuit. Moreover, this same dispute will occur again between Apotex and Pfizer regarding the drug Lipitor®. Thus, the underlying dispute here is not the rare, patent-specific event that Pfizer portrays it to be, but one that continues to plague Apotex and other generic companies.

Third, even if Pfizer's covenant and Teva's launch render this *particular* case moot, this dispute nonetheless falls squarely within the well-known "capable of repetition, yet evading review" exception to the mootness doctrine. The dispute already has occurred twice between Apotex and Pfizer, and undoubtedly will again. What's more, it will be too short in duration for meaningful review by this Court—Pfizer will see to that. The Court, therefore, should reject Pfizer's suggestion of mootness and grant the petition.

SUPPLEMENTAL REASONS FOR GRANTING THE PETITION

I. This Appeal Is Not Moot Because Apotex Retains A Legally Cognizable Interest In Its Outcome.

A case is moot "when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *City of Erie v. Pap's A.M.*, 529 U.S. 277, 287 (2000). Neither is true here. The FDA continues to delay Apotex's approval based on an exclusivity period that

should have been triggered *years* ago. Pfizer's covenant does nothing to alleviate this enormous harm.

But even after Apotex's generic product is approved upon expiration of Teva's exclusivity, the threat and potential for infringement liability remains for Apotex's customers and suppliers. Pfizer's covenant applies only to Apotex, and does not constitute an admission that the patent is invalid or not infringed by Apotex's generic product. The covenant does not apply to Apotex's customers, who may opt instead to purchase the product from another company, rather than undertake the risk of patent infringement liability. Only a judgment of non-infringement or invalidity can alleviate this harm and risk. *See Minnesota Mining and Mfg. Co. v. Norton Co.*, 929 F.2d 670, 673-74 and n.4 (Fed. Cir. 1991) (noting that Declaratory Judgment Act sought to alleviate problems caused by threat of infringement liability to 3M and its customers, and rejecting argument that threats to 3M's customers did not cause harm to 3M). Thus, Apotex retains a legally cognizable interest in the outcome of this litigation even after its generic product is approved.

II. Pfizer Cannot, Through Voluntary Conduct, Manipulate This Court's Jurisdiction To Insulate A Favorable Decision From Review.

"A case might become moot if subsequent events made it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 189 (2000); *accord United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953). But a "defendant's voluntary cessation of allegedly unlawful conduct ordinarily does not suffice to moot a case." *Friends of the Earth*, 528 U.S. at 174; *City of Mesquite v. Aladdin's Castle*, 455 U.S. 283, 289 (1983) (same). "If it did, the courts would be compelled to leave the defendant . . . free to return to his old ways." *Friends of the Earth*, 528 U.S. at 189. A "defendant claiming that its

voluntary compliance moots a case bears the formidable burden of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably expected to recur." *Id.* at 190; *see also Adarand Constructors v. Slater*, 528 U.S. 216, 222 (2000) (same). Here, Pfizer cannot satisfy its formidable burden because its wrongful behavior will recur absent review by this Court. Indeed, this case is not the first time that this dispute has occurred between Apotex and Pfizer, nor will it be the last.

In 2003, Apotex filed a declaratory judgment action in an effort to obtain patent certainty and approval of its generic equivalent of Pfizer's Accupril® after Pfizer delayed filing suit in order to delay Apotex's approval. *See* Addendum at ¶ 5. A district court granted Pfizer's motion to dismiss the suit for lack of a case or controversy because Pfizer itself refused to file suit. *See TorPharm, Inc. v. Pfizer, Inc.*, No. Civ. 03-990, 2004 WL 1465756 (D. Del. June 28, 2004). On appeal, upon learning that the reviewing panel included two judges (Mayer, J. and Gajarsa, J.) who previously had expressed the view that a case or controversy exists in this circumstance, Pfizer precluded review by the Federal Circuit by sending Apotex an unsolicited covenant. *See* Addendum at ¶ 5. Pfizer did so only after it had delayed Apotex's approval for as long as it could without risking appellate review of a decision in its favor. *See id.*

Significantly, the very same dispute between Apotex and Pfizer will occur again with respect to Pfizer's Lipitor®. *See* Addendum at ¶¶ 6-12. Pfizer already has obtained a judgment of infringement on the basic patent against the first generic company to file a paragraph IV ANDA challenging all of the Orange Book-listed patents. *Id.* at ¶ 8. This means that the first-filer cannot go to market until the basic patent (and its pediatric exclusivity) expire on September 24, 2009. *Id.* But because Pfizer did not assert several later-expiring patents, the approval of all other generic applicants will be

delayed, both by the first-filer's exclusivity (see 21 U.S.C. § 355(j)(5)(B)(iv)), and the possibility of potentially catastrophic infringement damages on those patents. *Id.*

Apotex has developed its own generic Lipitor® and intends to submit an ANDA shortly. *See* Addendum at ¶ 9. Apotex intends to launch its generic product in September 2009, once the basic patent expires, provided that it can obtain patent certainty on the unasserted Pfizer patents. *Id.* Without court decisions on those patents, Apotex's approval, as well as the approval of any other generic applicants, will be delayed well beyond the expiration of the basic patent. *Id.* As with Accupril® and Zoloft®, however, Pfizer will have no incentive to, and likely will not, sue Apotex, precisely because Pfizer can delay generic competition longer and create a bottleneck by delaying suit and avoiding a court decision on the later-expiring patents. *Id.* at ¶¶ 10-11. As with Accupril® and Zoloft®, Apotex will have no choice but to file a declaratory judgment action against Pfizer in order to get prompt approval and patent certainty.

Thus, Pfizer cannot show that its conduct will not recur, let alone that it is "absolutely clear" that such conduct will not recur. As a result, Pfizer's suggestion that there "is little reason to assume" and no "realistic possibility" that Apotex will face this situation again where a brand company uses a covenant not to sue to manipulate the Court's jurisdiction is disingenuous, if not absurd.

In *Pap's*, after prevailing below in a challenge to a public indecency ordinance, Pap's attempted to moot the case and preclude review by this Court with an affidavit stating that it had ceased the allegedly offending conduct (*i.e.*, the operation of a nude dancing establishment). *See* 529 U.S. at 287. Pap's argued that the case therefore was moot because the outcome of the case "will have no effect upon Respondent." *Id.* This Court disagreed, holding that Pap's voluntary cessation did not moot the case. *See id.* The

Court also held that the city had an ongoing injury because it could not enforce its ordinance, and that the availability of relief allowing the city to do so was "sufficient to prevent the case from being moot." *Id.* at 288. The Court also acknowledged that *Pap's* did not present "a run of the mill voluntary cessation case" because it was the party "who, having prevailed below, now seeks to have the case declared moot." *Id.* The Court thus held that its "interest in preventing litigants from attempting to manipulate the court's jurisdiction to insulate a favorable decision from review further counsels against a finding of mootness here." *Id.*

Here, nothing prevents Pfizer from engaging in the same conduct with Apotex, or another generic company, that gave rise to this dispute. Indeed, Pfizer already has done so with respect to Accupril® and Zoloft®. Reversing the decision below would allow Apotex to bring a declaratory judgment claim to prevent such harm in the future. Moreover, it is Pfizer, who, "having prevailed below, now seeks to have the case declared moot." *Pap's*, 529 U.S. at 288. As in *Pap's*, this Court's interest in preventing such manipulation counsels against a finding of mootness. Nothing in the cases Pfizer cites suggests that a party that prevailed below can so blatantly manipulate the Court's jurisdiction to insulate a favorable decision from review.

III. Alternatively, This Case Falls Squarely Within The "Capable Of Repetition, Yet Evading Review" Exception To The Mootness Doctrine.

A case is not moot if the "underlying dispute between the two parties is one capable of repetition, yet evading review." *Gannett Co. v. DePasquale*, 443 U.S. 368, 377 (1979). This exception applies where "(1) the challenged action was in its duration too short to be fully litigated prior to its cessation or expiration, and (2) there was a reasonable

expectation that the same complaining party would be subjected to the same action again." *Id.*

First, the same underlying dispute—*i.e.*, application of the Federal Circuit's "reasonable apprehension" test to a declaratory judgment action filed by a generic company—is certainly capable of repetition. As set forth in Section II, *supra*, this same dispute happened before between the same parties in Accupril®, and in all likelihood, will happen again between these parties over Lipitor®. *See* Addendum at ¶ 6. The same dispute also will arise between Apotex and other brand companies on other products. *See id.* at ¶¶ 13-14.

Pfizer's argument that the underlying dispute can never happen again because it has vowed never to sue Apotex on *this particular patent* over *this drug* reads this Court's precedent far too narrowly. Indeed, if that were the law, the "capable of repetition, yet evading review" exception could *never* apply to any aspect of a patent dispute. But this Court has never narrowed its application in this manner. In fact, this Court explicitly has held that the same controversy can recur when different subject matter or different parties are involved.

For example, in a long line of cases relating to court orders restricting media access to criminal proceedings, this Court recognized that the complaining parties may be injured by other, future orders concerning different proceedings or issued by other courts. The Court repeatedly has held that such situations qualify as "capable of repetition." *See Nebraska Press Ass'n v. Stuart*, 427 U.S. 539, 546 (1976) ("[t]he dispute between the State and the petitioners who cover events throughout the State" is "capable of repetition" because state prosecutors are authorized to seek restrictive orders in appropriate cases); *Ganne[illegible]* U.S. at 377-78 ("it is reasonably to be expected that t[illegible]petitioner, as publisher of two New York newspapers, will be subjected to similar closure orders entered by New York courts"); *Globe*

Newspaper v. Superior Court, 457 U.S. 596, 603 (1982) (it could reasonably be assumed that newspaper publisher would someday be subjected to further orders excluding it from courtrooms during testimony in other sex-offense trials); *Richmond Newspapers, Inc. v. Virginia*, 448 U.S. 555, 563 (1980) (noting that "other trials may be closed by other judges," making appeal of order excluding public and press from courtroom "capable of repetition, yet evading review"); *Press-Enterprise Co. v. Superior Court of Ca.*, 478 U.S. 1, 6 (1986) (controversy was "capable of repetition, yet evading review" because it could "reasonably be assumed that petitioner will be subjected to a similar closure order").

The Court also has held that the same controversy, despite having different underlying facts, can be "capable of repetition" in other analogous situations. For example, in *Securities and Exchange Comm'n v. Sloan*, the SEC said that it would no longer issue suspension orders against the respondent like the order at issue. *See* 436 U.S. 103, 108 (1978). The Court did not declare the dispute moot, finding a "reasonable expectation" that respondent would be subject to other orders suspending trading in the future, given the respondent's behavior and that the respondent owned other securities on which trading might also be suspended. *See id.* at 109-10. And in *Roe v. Wade*, the Court noted that "[p]regnancy often comes more than once to the same woman, and in the general population, if man is to survive, it will always be with us. Pregnancy provides a classic justification for a conclusion of nonmootness." 410 U.S. 113, 125 (1973).

Here, even if Pfizer (or another brand company) refuses to sue Apotex (or another generic company) on a different patent related to a different drug, the same controversy would repeat itself. Apotex has shown that the same controversy already has occurred between Apotex and Pfizer with respect to Accupril®, and will do so again for

Lipitor®. Pfizer's assertion that the issues are "highly fact-bound" (Pfizer Supp. Br. at 4) is belied by the repeated recurrence of this dispute between Apotex and Pfizer.[1] Thus, the controversy here undoubtedly is "capable of repetition."

Second, the challenged action always will be too short in duration for meaningful review because Pfizer always can give a covenant not to sue. Pfizer's own conduct allows the Court to disregard Pfizer's arguments to the contrary. Notwithstanding Pfizer's assertions about valuable patent rights and patentees not lightly or frequently relinquishing them (Pfizer Supp. Br. at 5), Pfizer itself has used covenants in two disputes involving Apotex in order to insulate a favorable decision from review. Every case involving this jurisdictional issue will be "short-lived" if the defendant is allowed to simply cease the controversy of its own accord after receiving a favorable appellate decision.[2]

Pfizer's conduct is analogous to the court orders in the SEC and court sealing cases, in which the orders expired before this Court could review the underlying issues. *See Sloan*, 436 U.S. at 109-10; *Nebraska Press Ass'n*, 427 U.S. at 546; *Gannett*, 443 U.S. at 377-78; *Globe Newspaper*, 457 U.S. at 603; *Richmond Newspapers*, 448 U.S. at 563; *Press-Enterprise*, 478 U.S. at 6. Here, Pfizer can argue that the case "expired," in effect, only because Pfizer decided it should, just as the courts and the SEC set limits on the lengths of their orders in those cases. And as in the voluntary cessation cases, this Court's "interest in preventing

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[1] Pfizer's assertion that the "statutory scheme has been fundamentally altered for future cases" is not true. *See* Pfizer Supp. Br. at 4. The ability of a generic company to obtain a declaratory judgment is, in fact, even more critical under the amended statute. *See* Apotex Reply Br. at 2-4.

[2] Pfizer's own argument that, if necessary, it could have mooted the *Teva* case at any time with a unilateral covenant not to sue destroys its reliance on the prior *Teva* litigation for the proposition that the dispute is not too short in duration. *See* Pfizer Supp. Br. at 5.

litigants from attempting to manipulate the Court's jurisdiction to insulate a favorable decision from review" should prevent Pfizer from unilaterally controlling the duration of the controversy in order to attempt to moot this case. *Pap's*, 529 U.S. at 288. This issue, largely through Pfizer's own conduct, has certainly evaded review, and will continue to do so as long as the defendants like Pfizer control the duration of the case.

CONCLUSION

The Court should reject Pfizer's suggestion of mootness and grant Apotex's petition for a writ of certiorari.

Respectfully submitted,

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September 19, 2006

No. 05-1006
IN THE

SUPREME COURT OF THE UNITED STATES

APOTEX INC. and APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

DECLARATION OF DR. BERNARD C. SHERMAN

I, DR. BERNARD C. SHERMAN, Ph.D., declare as follows:

1. I am the founder, Chairman and Chief Executive Officer of Apotex Inc. ("Apotex"), a Canadian-based pharmaceutical company that develops and manufactures quality generic medicines.

2. I have personal knowledge of the facts set forth herein, or believe them to be true based on my experience in the pharmaceutical industry and information I have received in the course of my duties, and am competent to testify to the same.

3. I submit this Declaration in response to Pfizer's supplemental brief and suggestion of mootness.

4. The underlying dispute between Apotex and Pfizer—regarding the Federal Circuit's application of its so-called reasonable apprehension test to the critical Hatch-Waxman declaratory judgment mechanism—already has occurred once between Apotex and Pfizer and I believe will recur again.

5. In 2003, Apotex filed a declaratory judgment action in an effort to obtain patent certainty and approval of its generic equivalent of Pfizer's Accupril®. A district court granted Pfizer's motion to dismiss the suit for lack of a case or controversy because Pfizer itself refused to file suit. On appeal, upon learning that the panel in the case included two judges (Mayer, J. and Gajarsa, J.) who had in previous cases expressed the view that a case or controversy exists in these circumstances, Pfizer attempted to preclude any meaningful review by the Federal Circuit by sending Apotex an unsolicited covenant not to sue—just as Pfizer has done in this case. Pfizer did so only after it had delayed Apotex's approval to the longest extent possible.

6. As with Pfizer's Accupril® in the prior case and Zoloft® here, the very same dispute between Apotex and Pfizer will occur again with respect to Pfizer's Lipitor®, the largest-selling prescription drug in the world today.

7. Pfizer has listed five (5) patents in FDA's Orange Book in connection with Lipitor®: U.S. Patent No. 4,681,893 ("the '893 patent"), expiring September 24, 2009 (with pediatric exclusivity to March 24, 2010); U.S. Patent No. 5,273,995 ("the '995 patent"), expiring December 28, 2010; U.S. Patent No. 5,686,104 ("the '104 patent"), expiring November 11, 2014; U.S. Patent No. 5,969,156

("the '156 patent"); and U.S. Patent No. 6,126,971 ("the '971 patent"), expiring January 19, 2013.

8. While the pertinent claim of the '995 patent has been held invalid, Pfizer already has obtained a judgment of infringement on the '893 patent against the first generic company to file a PIV ANDA challenging all of the Orange Book-listed patents. This means that the first-filer cannot go to market until the '893 patent (and its pediatric exclusivity) expire on September 24, 2009. But because Pfizer did not assert the later-expiring '104, '156 and '971 patents, the approval of subsequent generic ANDA applicants—even ones that have successfully designed around those patents—will be blocked and delayed, both by the first-filer's exclusivity, pursuant to 21 U.S.C. § 355(j)(5)(B)(iv), and the uncertainty associated with potentially catastrophic infringement damages on those patents.

9. Apotex has developed its own generic version of Lipitor® for which it intends to submit an ANDA shortly. Apotex intends to launch its generic product in September 2009 upon the expiration of the '893 patent, provided that Apotex can obtain patent certainty and court decisions on the unasserted Pfizer patents to clear the way for approval. Without court decisions on those patents, Apotex's approval, as well as the approval of any other generic applicants, will be delayed well beyond the expiration of the '893 patent.

10. As with Accupril® and Zoloft®, Pfizer will have no incentive to, and likely will not, sue Apotex, precisely because Pfizer can delay generic competition longer and create a bottleneck by delaying suit and avoiding any court decisions on the later-expiring '104, '156 and '971 patents.

11. In these circumstances, as with Accupril® and Zoloft®, Apotex will have no choice but to file another

declaratory judgment action against Pfizer in order to obtain approval of its product and patent certainty. This is the very same dispute that already occurred with respect to Accupril® and in the present case regarding Zoloft®. As before, Pfizer can attempt to manipulate the Court's jurisdiction yet again and preclude meaningful review by this Court by giving Apotex an unsolicited covenant not to sue.

12. The underlying dispute and circumstances of this case will continue to occur between Apotex and Pfizer as long as Pfizer is permitted to manipulate the Court's jurisdiction and insulate a favorable decision from review.

13. Furthermore, Apotex also has brought declaratory judgment claims against another brand company, Janssen, in connection with Apotex's attempt to market a generic version of Risperdal®. Janssen, like Pfizer, refused to bring suit against Apotex on the latest expiring listed patents. Once Apotex asserted its claims on these patents, Janssen moved to dismiss Apotex's declaratory judgment claims, citing, among other things, the Federal Circuit decision that Apotex asks this Court to review here.

14. Finally, Apotex has filed an ANDA for Trileptal®. Should Novartis Pharmaceuticals follow Pfizer's lead and attempt to delay approval of Apotex's ANDA by refusing to bring an infringement suit, Apotex will have no choice but to consider declaratory judgment claims in that situation as well.

15. The foregoing facts are true and correct as I verify and believe.

Dated this 14th day of September, 2006.

I, DR. BERNARD C. SHERMAN, hereby declare, under penalty of perjury under 28 U.S.C. § 1746 and the laws of the United States of America, that the foregoing Declaration is true and correct.

__/s/__Signature_____
DR. BERNARD C. SHERMAN

(4)

No. 05-1006

In the Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

FEDERAL STATUTES

FEDERAL RULES

INTRODUCTION

The Federal Circuit has introduced into Article III a limitation on the subject matter jurisdiction of federal courts in declaratory judgment actions that runs contrary to established precedent of this Court, and that decisions of other circuits have rejected. Further, by its ruling, the court of appeals denied jurisdiction in a class of federal cases in which Congress specifically authorized declaratory judgment actions in order to accelerate the introduction of generic drugs and thereby moderate the explosive growth in expenditures on prescription drugs.

Pfizer's opposition ignores this Court's settled Article III jurisprudence, the decisions of other circuits applying this jurisprudence, and the importance of the questions presented for national health care policy. The petition for a writ of certiorari should be granted.

I. The Issues Presented For Review Will Continue To Affect Consumers And ANDA Applicants For Years, If Not Decades, To Come.

Pfizer states that Apotex's petition "raises no important or recurring issue warranting this Court's review . . . ." (Pfizer Opp'n at 9). This is so, according to Pfizer, "because of amendments to the key provisions of the statute . . . ." (*Id.* at 10). Pfizer is wrong. The issues presented here will continue to severely harm ANDA applicants and the public as long as the *Teva* decision remains in effect.

As an initial matter, Pfizer advanced this "unlikely to recur" argument when opposing Teva's certiorari petition in September 2005. This case amply demonstrates the fallacy of Pfizer's argument, as the very same legal dispute has arisen yet again. Indeed, this exact same legal issue would have reached this Court earlier had Pfizer not manipulated the system to moot Apotex's attempt to challenge

the *Teva* decision last year.[1] And the Generic Pharmaceutical Association highlights the sweeping effect that the *Teva* decision is having on other generic manufacturers also attempting to resolve patent issues such as those presented here. (*See* GPhA Amicus Br. at 18-19). Thus, the *Teva* decision inevitably will continue to directly injure consumers and the public health unless addressed by this Court.

Equally as important, the harm caused by the Federal Circuit's erroneous decision will continue to plague generic drug companies and consumers for years to come. Pfizer claims that enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (the "Medicare Amendments"), so altered the Hatch-Waxman Act scheme that the questions presented in Apotex's petition will not arise in the future. (*See* Pfizer Opp'n at 10-14). Not so.

First, the changes to which Pfizer refers only apply to drug products for which the first ANDA containing a so-called "Paragraph IV" certification was filed *after* December 8, 2003. Thus, many, many ANDAs continue to be controlled by the statutory scheme at issue in this appeal. The significant legal issues raised herein will, therefore, continue to exist for years.

Second, court decisions continue to play a key role with respect to ANDAs governed by the new Medicare Amendment provisions. Before the Medicare Amendments, a judgment of invalidity, unenforceability, or noninfringement of an Orange Book patent triggered the first

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[1] In 2003, Apotex filed a declaratory judgment action in an effort to obtain patent certainty with respect to its generic equivalent of Pfizer's Accupril®. A district court dismissed the suit, however, for lack of a case or controversy because Pfizer itself refused to file suit. *See TorPharm, Inc. v. Pfizer Inc.*, No. Civ. 03-990-SLR, 2004 WL 1465756 (D. Del. June 28, 2004). Apotex appealed. Upon learning that the panel in the case included two judges (Mayer and Gajarsa) who had in previous cases expressed the view that a case or controversy exists in these circumstances, Pfizer mooted Apotex's appeal by sending it a covenant not to sue. *See Apotex v. Pfizer*, 125 Fed. Appx. 987 (Fed. Cir. 2005).

ANDA filer's 180-day exclusivity period. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II). As Pfizer points out, those Amendments removed court decisions as something that can trigger generic exclusivity. From this, Pfizer suggests that the Medicare Amendments eliminated the "concern" that led to Apotex's declaratory judgment suit (and similarly to Teva's). (Pfizer Opp'n at 11). This, too, is incorrect.[2]

While the Medicare Amendments removed court decisions as something that could "trigger" the start of the 180-day generic exclusivity period, the Amendments did not eliminate the importance of court decisions. Indeed, Congress elevated such decisions to a position of greater consequence—court decisions now cause an ANDA applicant to *forfeit exclusivity entirely*, and not just start the 180-day clock running. Specifically, under the Medicare Amendments, if the first ANDA filer does not launch its generic product within 75 days of such a judgment, the first filer forfeits its exclusivity altogether. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb), (j)(5)(D)(ii).[3] Thus, the need to ob-

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[2] Pfizer's argument also is nonsensical because it leaves unexplained why Congress would specifically provide for a declaratory judgment remedy for generic companies in the very amendments that, according to Pfizer, eliminated the need for the remedy. Indeed, one searches Pfizer's opposition (and the decision below) in vain for any explanation as to why Congress would go to the trouble of amending the Hatch-Waxman Act specifically to authorize declaratory judgment actions if, as Pfizer contends, Congress simply intended to maintain the legal *status quo*.

[3] In full, the so-called "failure to market" forfeiture provision provides that exclusivity is forfeited if:

> The first applicant fails to market the drug by the later of—
>
> (aa) the earlier of the date that is—
>
> (AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or
>
> (BB) 30 months after the date of submission of the application of the first applicant; or

tain court decisions using the declaratory judgment provisions that Congress included in the Medicare Amendments remains and, in fact, is more critical now than ever.[4]

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) [of this section] is withdrawn by the holder of the application approved under subsection (b) [of this section].

21 U.S.C. § 355(j)(5)(D)(i)(I).

[4] Pfizer points to an earlier version of the Medicare Amendments that would have deemed an Orange Book patentee's failure to commence an infringement suit to "establish[] an actual controversy . . . sufficient to confer subject matter jurisdiction . . . ." (Pfizer Opp'n at 25 (citation omitted)). But Congress rejected this version, not because it sought to preserve the "reasonable apprehension" test, as Pfizer argues, but rather because the Justice Department advised Congress that the attempt to define an "actual controversy" would usurp the power of the courts to determine the scope of Article III. (*See* Br. of United States Senators Edward M. Kennedy, John S. McCain, and Charles E. Schumer as *Amicus Curiae* in Support of Petition of Teva Pharmaceuticals USA, Inc. for Rehearing or Rehearing *En Banc* at 4-5, No. 04-1186 (Fed. Cir.)). The bill, as enacted, preserved the proper sphere of judicial authority by creating a cause of action, and directing courts to exercise jurisdiction unless it would violate Article III to do so.

Finally, the important legal issues raised by Apotex's petition are not "narrowly fact-intensive" or "unusual" issues unsuited for certiorari review, as Pfizer argues. (*See* Pfizer Opp'n at 12-13). While the application of the Federal Circuit's "reasonable apprehension of imminent litigation" test may at times turn on the particular facts of a case, the question of whether that test is mandated by Article III purely is a legal issue.

For these reasons, Pfizer's arguments against granting certiorari lack merit. The issues raised herein undoubtedly are appropriate for review by this Court. *See* SUP. CT. R. 10.

II. Apotex's Claim For Declaratory Relief Is Ripe.

Pfizer tries to avoid the fact that the decision below represents a split in the circuit and an impermissible departure from this Court's Article III precedent by attempting to re-cast that decision as an application of settled ripeness principles. (Pfizer Opp'n at 14-15). Pfizer's attempt fails. Neither the Federal Circuit nor Pfizer ever characterized the issue here in ripeness terms, or invoked this Court's ripeness cases in support of the denial of subject matter jurisdiction. They failed to do so for good reason. Under this Court's formulation of the test for ripeness—which Pfizer never mentions—Apotex's declaratory judgment action is ripe. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967) (requiring courts "to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration").

Apotex seeks to resolve a patent infringement claim where an act of infringement already has occurred. By statute, Apotex's submission of an ANDA containing a Paragraph IV certification constitutes a statutory act of infringement. 35 U.S.C. § 271(e)(2). As this Court has stated, Congress created this statutory provision for the express purpose of creating an actual controversy sufficient to support judicial resolution of disputes concerning the application of Orange Book patents to proposed generic drugs.

See Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990).

Pfizer cannot deny that an infringement claim in response to a generic company's submission of an ANDA with a Paragraph IV certification would be ripe. Pfizer has commenced such actions many times, including one against IVAX on the very patent at issue here. Under well-settled law from this Court, if Pfizer could have asserted a ripe claim for patent infringement against Apotex, then Pfizer cannot dispute the ripeness of Apotex's declaratory judgment action to resolve the identical claim: "It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed; the [justiciability] inquiry is the same in either case." *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (citation omitted). If Apotex's infringement claim is unripe, then so is the infringement claim authorized by 35 U.S.C. § 271(e)(2), but as this Court previously observed, without suits, the Hatch-Waxman Act scheme simply "will not work." *Eli Lilly*, 496 U.S. at 678.

Moreover, unlike the claims in cases such as *Texas v. United States*, 523 U.S. 296, 300 (1998) (*see* Pfizer Opp'n at 15), Apotex's claim does not "rest[] upon contingent future events that may not occur as anticipated, or indeed may not occur at all." Apotex's submission of a Paragraph IV ANDA constitutes a statutory act of infringing Pfizer's patent. The patent's validity depends on facts antedating its issuance, and resolution of the infringement claim turns on applying the claims in that patent to a drug product that Apotex already has developed, manufactured, and described in great detail in its ANDA. Given these undisputed facts, there is nothing contingent or hypothetical about the claim that Apotex seeks to resolve and, therefore, this is not a case in which "the courts would benefit from further factual development of the issues presented." *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998).

Further, Apotex does not seek to challenge a statute that may never be enforced or whose enforcement is committed to other branches of government. *Cf. Boyle v. Landry*, 401 U.S. 77, 80-81 (1971) (declining to enjoin enforcement of criminal statutes at the behest of individuals who have never even been threatened with prosecution; companion case to *Younger v. Harris*, 401 U.S. 37 (1971)).[5] Congress specifically bestowed sole responsibility on federal courts to hear and decide declaratory judgment actions brought by ANDA applicants under the circumstances presented here.

In sum, the infringement and validity issues raised in Apotex's complaint are fit for judicial resolution. No further factual development is needed to resolve them, and there is no question that Apotex faces hardship if these issues are not resolved. The Federal Circuit so recognized, (*see* Pet. App. at 40a), and Pfizer has not disputed this point (*see* Pfizer Opp'n at 11, 24). Thus, Apotex's claim is ripe for judicial review.

III. The Federal Circuit Ruling Below Conflicts With Prior Decisions Of This Court And Other Circuits.

One of the principal purposes of the Declaratory Judgment Act was to allow competitors to obtain "patent certainty" in the face of what an earlier Federal Circuit decision referred to as a "Damoclean threat with a sheathed sword." *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988) (citation omitted). Sixteen years later, the panel majority in *Teva* changed its mind in, ruling that companies like Apotex cannot seek de-

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[5] Pfizer's suggestion that "[t]he Federal Circuit's 'reasonable apprehension' test is a well-established analogue to the imminent threat of prosecution standard," (Pfizer Opp'n at 16), falls far wide of the mark. The federalism concerns that underlie cases such as *Boyle* (*id.* at 15-16) are immaterial here. Nor is there any administrative action with which resolution of Apotex's lawsuit will interfere. On the contrary, under the Hatch-Waxman Act, the timing of FDA action depends on judicial resolution of patent disputes.

claratory relief unless the sword is out of the sheath and, further, that Article III mandates this result. That ruling is, therefore, inconsistent with the Article III jurisprudence of this Court and of other circuit courts. None of Pfizer's arguments to the contrary—which merely mischaracterize the decisions cited in Apotex's Petition—changes this fact. Pfizer necessarily fails to reconcile the Federal Circuit's "reasonable apprehension of imminent litigation" requirement with the Article III decisions of this Court and the decisions from other circuits that have applied this Court's decisions.

Pfizer argues that declaratory judgment claims in *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227, 237 (1937), were proper in that case because the declaratory judgment defendants had placed Aetna on notice of an adverse legal position by claiming disability benefits in 1930 and 1931. (*See* Pfizer Opp'n at 18). This Court's opinion, however, never suggests that suit by the declaratory judgment defendants was "imminent" based on legal positions staked out several *years* before Aetna brought suit in 1934. This Court found the controversy to be justiciable because the issues were, as they are here, concrete, and a decision on them would conclusively resolve an existing legal dispute.

Pfizer attempts to undermine the significance of this Court's decision in *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83 (1993), by suggesting that it was a ripeness action and that the decision was consistent with the reasonable apprehension test in requiring the prospect of imminent suit. (Pfizer Opp'n at 17). Again, not so. In that decision, the Court expressly recognized "the sad and saddening scenario that led to enactment of the Declaratory Judgment Act" and that the mere "desire to avoid the threat of a 'scarecrow' patent . . . may therefore be sufficient to establish jurisdiction under the Declaratory Judgment Act." *Cardinal Chem.*, 508 U.S. at 95-96.

These are the very circumstances supporting jurisdiction under the Hatch-Waxman Act in this appeal.

Pfizer attempts to explain away the decisions from other circuits that reject the Federal Circuit's "reasonable apprehension of imminent suit" requirement, but Pfizer's efforts are not persuasive. (*See* Pfizer Opp'n at 18-19). Pfizer, for example, reads *United Christian Scientists* and *Sherwood Medical Industries* as consistent with the Federal Circuit's ruling (Pfizer Opp'n at 18-19), only by ignoring what the District of Columbia and Eighth Circuits, respectively, actually said in each of those cases. The courts in both of those cases recognized, among other things, that the *threat* of an infringement suit, even if implicit, would support a justiciable controversy. *United Christian Scientists v. Christian Sci. Bd. of Directors, First Church of Christ, Scientist*, 829 F.2d 1152, 1158 n.25 (D.C. Cir. 1987); *Sherwood Med. Indus., Inc. v. Deknatel, Inc.*, 512 F.2d 724, 727-28 (8th Cir. 1975). In addition, those circuits also accorded weight to the fact that the patentee had previously brought infringement actions. *See United Christian Scientists*, 829 F.2d at 1158 n.25; *Sherwood Med.*, 512 F.2d at 728. The circumstances here meet the standards applied by these circuits, particularly in light of Pfizer's representation that the '699 patent could be involved as a basis for infringement and Pfizer's prior suit against IVAX on the same patent at issue here. And, of course, Pfizer does not dispute that the court in *Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14 (1st Cir. 2001), did not require the plaintiff to prove that he faced a reasonable apprehension of suit. *Sallen*, 273 F.3d at 25. Indeed, the contours of the dispute between Apotex and Pfizer are no less certain than they were in *Sallen*: the issue is whether Pfizer's patent is valid, and whether Apotex's generic sertraline product infringes.

In the end, Pfizer cannot avoid this Court's decisions defining Article III's "constitutional minimum" in terms of injury in fact attributable to the defendant's conduct that is redressable by the relief requested. Nor can

Pfizer avoid the fact that the Federal Circuit's decision below, which elevates the "reasonable apprehension" test to a Constitutional requirement, plainly is inconsistent with this Court's Article III decisions.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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April 24, 2006

No. 05-1006

In the Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF *AMICUS CURIAE* OF THE GENERIC PHARMACEUTICAL ASSOCIATION IN SUPPORT OF PETITIONERS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

FEDERAL STATUTES

OTHER AUTHORITIES

INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae Generic Pharmaceutical Association (GPhA) represents over 120 companies that manufacture more than ninety percent of all affordable prescriptions dispensed in the United States each year, accounting for more than one billion prescriptions annually. GPhA accordingly has a significant interest in the proper construction of the so-called Hatch-Waxman scheme, which Congress enacted to speed the marketing of generic drugs while, at the same time, protecting the legitimate patent rights of brand companies.

STATEMENT OF THE CASE

I. Background to the Statutory Scheme

In the 1984 Hatch-Waxman Amendments to the federal patent and drug laws, Congress sought to ameliorate two substantial obstacles to the efforts of generic drug manufacturers to compete against brand manufacturers. First, Congress created a streamlined process for FDA approval of generic drug products through which generic manufacturers may submit an Abbreviated New Drug Application (ANDA) demonstrating the bioequivalence of the so-called "pioneer" product and its generic equivalent. 21 U.S.C. § 355(j)(2)(A).

Second, Congress adopted a scheme to expedite the litigation of patent disputes. Generic manufacturers, which seek to compete with brand products already in the marketplace, often face the prospect of patent infringement suits by brand companies. Such suits, if successful, could result in debilitating liability if the generic drug were marketed but

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[1] Pursuant to SUP. CT. R. 37.6, *amicus* GPhA states that, for this Brief, counsel for Apotex slightly revised and updated factually GPhA's *Amicus Curiae* brief previously submitted in support of Teva's petition for *writ of certiorari* in *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, no. 05-48 (S. Ct.), and that Apotex contributed financially to the preparation and submission of this Brief. Letters reflecting the consent (or lack of objection) of all parties to the filing of this Brief have been lodged with the Court.

later found to infringe the patent. Thus, as Congress knew, in cases of genuine doubt, generic manufacturers may decline to launch their less-expensive products, even if the brand company's patent claims ultimately would have failed.

Congress thus created a statutory mechanism to permit early resolution of potential patent infringement claims against a new generic drug prior to its marketing. Under Hatch-Waxman, brand manufacturers must identify any patent for which "a claim of patent infringement could reasonably be asserted" against the maker of a generic equivalent. 21 U.S.C. §§ 355(b)(1), (c)(2). FDA publishes that patent information in its "Orange Book." In turn, a generic manufacturer's submission of an ANDA challenging the validity, unenforceability, or infringement of an Orange Book-listed patent constitutes a statutory act of patent infringement, vesting federal courts with subject matter jurisdiction over an infringement suit. 35 U.S.C. § 271(e)(2).

Congress contemplated that these provisions would resolve patent disputes soon after the ANDA is filed. To encourage generic companies to avail themselves of these new statutory provisions, Congress amended the statutory scheme in other ways as well. For example, Congress created an incentive for brand companies to bring a patent infringement claim after learning of the ANDA filing. If a brand company initiates patent litigation within forty-five days of receiving notice of an ANDA applicant's challenge to its patent, FDA must defer approval of the generic product for thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

Congress also encouraged generic drug development by providing that the owner of the first ANDA containing a challenge to a listed patent receives a 180-day period of marketing exclusivity against other generic competitors for that drug product. 21 U.S.C. § 355(j)(5)(B)(iv). Specifically, FDA must defer approval of later-filed applications until 180 days after the earlier of two specified dates. *Id.* Of particular relevance to this case is the fact that a later generic applicant can trigger the start of this 180-day period by ob-

taining a judgment declaring the listed patent invalid, unenforceable, or not infringed. *Id.*

The Hatch-Waxman provisions were only a partial success, however. Through various tactics, brand companies could use the exclusivity period granted to first ANDA filers to block later generic competitors from the marketplace for years. Despite the thirty-month stay that would result if a brand company initiated suit within the forty-five day Hatch-Waxman window, brand companies often had a substantial incentive to refrain from instituting litigation before the generic drug was brought to market. A judicial determination could produce a finding of non-infringement that would trigger the start of the 180-day exclusivity period, thereby allowing more generic companies to enter the market sooner. Declining to institute patent litigation also can create a cloud of patent uncertainty that delays generic market entry longer than a patent suit itself.

District courts often have ruled that declaratory judgment actions must be dismissed for failure to satisfy the Federal Circuit's "reasonable apprehension" test. Even though Congress clearly contemplated that generic manufacturers would be permitted to resolve patent claims through a declaratory judgment suit against the patentee, the Federal Circuit, with exclusive jurisdiction over patent appeals, has held that such a suit was impermissible unless the plaintiff itself faced a reasonable apprehension of suit from the patentee. *See, e.g., BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993). That rule rested on the court's "pragmatic" concern that merely obtaining a patent should not subject the patentee to litigation. *Id.*

In response to these continuing impediments, Congress enacted further legislation in 2003 "to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies." H.R. CONF. REP. NO. 108-391, at 836 (2003). As amended, the legislation provides that, if the brand company does not bring suit within the forty-five day Hatch-Waxman period, the generic

competitor may itself institute a declaratory judgment action. 21 U.S.C. § 355(j)(5)(C). Recognizing its power to remove the Federal Circuit's prudential standing barrier, Congress further provided that the district courts would have jurisdiction over such a suit to the fullest "extent consistent with the Constitution." 35 U.S.C. § 271(e)(5).

II. The Instant Litigation And Lower Court Rulings

1. This case arises from petitioners Apotex Inc.'s and Apotex Corp.'s (Apotex) intention to market a generic equivalent to respondent Pfizer's antidepressant Zoloft® (sertraline hydrochloride). As is relevant here, Pfizer listed in the Orange Book two patents in connection with Zoloft®. According to Pfizer, one of these patents expires in 2006; the other (known as the '699 patent") expires in 2010.

In 2003, Apotex filed an ANDA for a generic equivalent of Pfizer's Zoloft®. Apotex represented in its ANDA that it intended to begin marketing as soon as Pfizer's first patent (the '518 patent) expired in 2006. Apotex further represented that the '699 patent either would not be infringed or was invalid. Apotex's ANDA submission constituted a technical act of infringement of the '699 patent. However, Pfizer did not sue Apotex. Pfizer knew that its refusal to bring suit would impede and delay competition by Apotex in at least two ways. First, such refusal would create a cloud of patent uncertainty, threatening Apotex with the prospect of massive patent liability if it brought its drug to market before the '699 patent expired in 2010. Second, by avoiding a resolution of the patent dispute, Pfizer prevented FDA from approving Apotex's product until at least 180 days *after* Pfizer's first patent expired in 2006. Pfizer was successfully able to avoid resolving the dispute by entering into a side agreement with another generic manufacturer, Ivax, which filed the first ANDA for sertraline and thus had a right to generic exclusivity for its sertraline product. Pfizer had sued Ivax for patent infringement in response to Ivax's ANDA, but settled in exchange for a share of the revenues from Ivax's sales. Apotex could avoid or limit this additional 180-

day delay, however, if it secured a court judgment that Pfizer's '699 patent was either invalid or not infringed prior to the expiration of Pfizer's first patent. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

2. To remove the cloud of patent uncertainty over its product, and to avoid the delay in FDA approval resulting from the Pfizer/Ivax agreement, Apotex brought its declaratory judgment action against Pfizer. The district court, however, misapplied this Court's precedent and prior Federal Circuit precedent to hold that Apotex's claim was not ripe. (*See* Pet. App. 2a-15a). The district court did not doubt that Apotex was injured by its inability to enter the marketplace based upon a failure to resolve the patent controversy. Indeed, the district court recognized the "gaming of the system" by brand companies. (*Id.* 4a-5a). Nonetheless, the district court concluded that it was required by Federal Circuit precedent to dismiss the suit for lack of a justiciable case or controversy because Apotex did not have a "reasonable apprehension" that it would be sued by Pfizer. (*Id.* 12a-15a).

The Teva Decision

3. Apotex appealed. While that appeal was pending, the Federal Circuit decided *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005) (Pet. App. 16a-49a), *reh'g denied*, 405 F.3d 990 (Fed. Cir. 2005) (Pet. App. 50a-68a), *cert denied*, 126 S. Ct. 473 (2005), which involved the justiciability of another generic manufacturer's declaratory judgment action against Pfizer regarding the same drug product at issue here, sertraline hydrochloride. (Pet. App. 16a-17a). Teva, joined by the AARP and the Federal Trade Commission (FTC) as *amicus curiae*, argued that a justiciable case or controversy existed on these recurring facts.[2] The FTC emphasized the "important role" this case would play "in furthering competitive pharmaceutical markets and in

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[2] FTC's brief (FTC Panel Br.) is available at http://www.ftc.gov/ogc/briefs/teva_v_pfizer.pdf.

lowering health care cost[s]." (FTC Panel Br. 3). "This issue has important ramifications for the operation of Hatch-Waxman because such a declaratory judgment action" may be "the *only* means by which a generic drug maker may be able to" bring a competing product to market. (*Id.* (emphasis added)). The FTC explained: "If the district court's decision is upheld, it will enable first generic applicants and brand-name drug manufacturers to delay substantially entry by other generic firms, and indeed by *any* generic firm (including one that has done a better job of designing around the patent), into the marketplace for a drug." (*Id.* 3-4).

A divided panel of the Federal Circuit nonetheless affirmed the *Teva* lower court decision. (Pet. App. 41a). The panel majority acknowledged this Court's prior holding that the existence of an "actual controversy" sufficient to bring a declaratory judgment action depends on "'whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" (*Id.* 26a).

Teva's brief demonstrated that there was indeed a concrete controversy between it and Pfizer. For example, by listing its patents in the Orange Book, Pfizer had declared that Zoloft® was protected by the '699 patent, whereas Teva contended that the '699 patent did not preclude its market entry. Pfizer moreover previously had invoked that patent to sue Ivax when Ivax sought to introduce a generic equivalent for Zoloft®. Though Teva's ability to bring its product to market was directly precluded by Pfizer's conduct, Pfizer had refused Teva's request for a covenant not to sue. Despite these undisputed facts, the Federal Circuit concluded that its so-called "reasonable apprehension" test is a constitutional threshold for bringing a declaratory judgment action. (*See* Pet. App. 33a-34a). The court held that a declaratory judgment action is justiciable only if there is "an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment

plaintiff that it will face an infringement suit." (*Id.* 27a). Indeed, according to the Federal Circuit, the declaratory judgment plaintiff must "demonstrate that it has a reasonable apprehension of [an] *imminent* suit." (*Id.* 30a).

The panel majority concluded that Teva could not meet this rigorous standard because the very point of Teva's claim was that Pfizer sought to *avoid* a court adjudication of the dispute: "Significantly, Teva virtually concedes that Pfizer will not bring immediate suit for infringement of the '699 patent. According to Teva, Pfizer does not wish to expose the patent to the possibility of a noninfringement or invalidity determination. . . ." (Pet. App. 31a). The majority found it irrelevant that Teva was injured by this state of affairs:

> The fact that Teva is disadvantaged from a business standpoint . . . and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. *It is not the product of a threat of suit by Pfizer. That is the problem that Teva faces in seeking to establish district court jurisdiction.*

(*Id.* 40a (emphasis added)). The court continued:

> [I]n order to rule in Teva's favor, we would have to hold that the Article III requirement of an actual controversy is satisfied, not because Teva is under an imminent threat of suit by Pfizer, but because the combined circumstances of the Hatch-Waxman scheme and Pfizer's lawful conduct under that scheme have created a situation in which Teva finds itself at a competitive disadvantage. . . . Those circumstances do not amount to an actual controversy between Teva and Pfizer, however.

(*Id.*).

4. Teva petitioned for rehearing *en banc*, again supported by amicus FTC (FTC En Banc Br.). The petition was denied over the dissenting votes of three judges who issued two dissenting opinions. (Pet. App. 51a). Teva subsequently filed a petition for writ of certiorari with this Court. In its opposition to that petition, Pfizer argued that Teva's claimed controversy "will almost certainly never ripen into any actual dispute in light of its acquisition of Ivax." (Respondent's Br. at 10). The Supreme Court agreed and denied Teva's petition. *Teva*, 126 S. Ct. 473.

The Current Appeal

5. Before the Federal Circuit here, Pfizer argued that Apotex's appeal was controlled by the Federal Circuit's *Teva* ruling. The Federal Circuit agreed, summarily affirming the judgment dismissing Apotex's suit. (Pet. App. 1a).

REASONS FOR GRANTING THE WRIT

Apotex's petition for certiorari should be granted for at least two reasons. First, the Federal Circuit's decision is flatly contrary to this Court's precedents identifying the "case or controversy" required to invoke the jurisdiction of the federal courts. The ruling below moreover conflicts with decisions of other circuits that faithfully apply this Court's decisions. Second, the question also is of indisputable importance. This Court has in the past granted certiorari to review important rulings of the Federal Circuit on questions of patent law, and it should do so here.[3] This case also is an ideal vehicle to resolve the questions presented. Apotex's claim against Pfizer presents two distinct injuries that, in *amicus*'s view, give rise to an Article III case or controversy. Apotex is both (a) precluded from securing FDA approval,

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[3] For recent examples, *see Medimmune, Inc. v. Genentech, Inc.*, 126 S. Ct. 1329 (2006); *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 601 (2005); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005); *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002).

and (b) deterred from entering the market, resulting from the prospect of patent liability. By granting the petition, the Court can address in one case whether either or both injuries are sufficient to trigger the jurisdiction of the federal courts.

Certiorari accordingly should be granted. At the very least, the Court should invite the Solicitor General and the Federal Trade Commission to file briefs expressing the views of the United States.

I. The Federal Circuit's Decision Is Contrary To This Court's Precedents Defining The "Case Or Controversy" Required By Article III And Further Conflicts With The Precedent Of Other Circuits.

1. Congress has granted the federal courts jurisdiction to decide declaratory judgment suits brought by generic manufacturers against brand manufacturers to resolve patent claims to the fullest "extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). The Federal Circuit held that the Constitution prohibits such a suit unless the generic manufacturer "has a reasonable apprehension of *imminent* suit" by the brand-name manufacturer. (Pet App. 30a).

This ruling cannot be reconciled with this Court's precedents. "The 'irreducible constitutional minimum of standing,'" this Court has held, "contains three requirements":

> First and foremost, there must be alleged (and ultimately proved) an "injury in fact"–a harm suffered by the plaintiff that is "concrete" and "actual or imminent, not 'conjectural' or 'hypothetical.'" Second, there must be causation–a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant. And third, there must be redressability–a likelihood that the requested relief will redress the alleged injury.

Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 103 (1998) (citations omitted).

The Federal Circuit held that Apotex failed to meet the first standing requirement because the only injury it was willing to recognize—a suit by Pfizer—was insufficiently "imminent." That holding is clearly wrong. This Court's precedents require that the *injury* be "imminent," as opposed to "conjectural" or "hypothetical." There is no requirement that *litigation* filed by the other side must be imminent. Put another way, Article III provides for jurisdiction not merely when there is a "case," but also when there is a "controversy." That requirement is satisfied in these circumstances.

The Federal Circuit's contrary holding is flatly at odds with this Court's decision in *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83 (1993), addressing the circumstances in which Article III of the U.S. Constitution permits a declaratory judgment action with respect to a patent infringement claim. Recognizing that "a party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy," this Court explained that "[i]n patent litigation, a party may satisfy that burden, and seek a declaratory judgment, even if the patentee has not filed an infringement action." *Cardinal Chem.*, 508 U.S. at 95. In support, this Court quoted with approval Judge Markey's opinion in *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-35 (Fed. Cir. 1988), recognizing that cases such as this present:

> the sad and saddening scenario that led to enactment of the Declaratory Judgment Act . . . . In the patent version of that scenario, a patent owner engages in a *danse macabre*, brandishing a Damoclean threat with a sheathed sword. . . . Before the Act, competitors victimized by that tactic were rendered helpless and immobile so long as the *patent owner refused to grasp the nettle and sue*. After the Act, those competitors were no longer restricted to an *in terrorem* choice between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises; they could clear the air by

> suing for a judgment that would settle the conflict of interests. *The sole requirement for jurisdiction under the Act is that the conflict be real and immediate, i.e., that there be a true, actual "controversy" required by the Act.*

Cardinal Chem., 508 U.S. at 95-96 (emphasis added). As demonstrated here, the Federal Circuit refuses to heed *Cardinal Chemical*, instead insisting that a declaratory judgment plaintiff have not only a real and immediate controversy with the defendant, but also the prospect of imminent suit.

Outside the patent context, this Court's seminal ruling "upholding the [declaratory judgment] statute" involved, as Judge Dyk explained in his dissenting opinion in *Teva*, a situation precisely analogous to the one here—"one in which there was no imminent risk of suit because the potential plaintiff declined to sue." (Pet. App. 63a (citation omitted)). In *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227 (1937), the plaintiff insurance company sought a declaration of its obligations to the policyholders. Not only had the policyholders "not instituted any action wherein the plaintiff would have an opportunity to prove the absence of the alleged disability," *Aetna Life*, 300 U.S. at 239, but Aetna sued for the very reason that there was no present prospect of the parties' rights being adjudicated. This Court nonetheless found a sufficient controversy because the case involved a "definite and concrete" dispute relating to the parties' "legal rights and obligations." *Id.* at 242. "Where there is such a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged, the judicial function may be appropriately exercised although the adjudication of the rights of the litigants may not require the award of process or the payment of damages." *Id.* at 241 (citations omitted).

Prior to the transfer of exclusive jurisdiction of such questions to the Federal Circuit, the regional circuits faithfully applied this Court's precedents in analogous circum-

stances.[4] The Eighth and District of Columbia Circuits considered whether the plaintiff had a reasonable apprehension that it will face either an infringement suit or *the threat of one, rather than* whether the plaintiff had a reasonable apprehension of an imminent suit. *See, e.g., United Christian Scientists v. Christian Sci. Bd. of Directors, First Church of Christ, Scientist*, 829 F.2d 1152, 1158 n.25 (D.C. Cir. 1987); *Sherwood Med. Indus., Inc. v. Deknatel, Inc.*, 512 F.2d 724, 727-28 (8th Cir. 1975). That standard is met here, as Apotex unquestionably faced a reasonable threat of suit given that Pfizer listed the '699 patent in the Orange Book, failed to provide Apotex with any reassurance that it will not sue Apotex or that Apotex's generic will not infringe the '699 patent, and sued Ivax for patent infringement.[5]

Two other circuits similarly applied a less stringent standard than the Federal Circuit's. The Ninth Circuit considers whether "the plaintiff has a real and reasonable apprehension that he will be subject to liability"—a fact-based determination that looks at "[t]he acts of the defendant . . . in view of their likely impact on competition and the risks imposed upon the plaintiff, to determine if the threat perceived by the plaintiff [is] real and reasonable." *Chesebrough-Pond's, Inc. v. Faberge, Inc.*, 666 F.2d 393, 396 (9th Cir.

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[4] This Court's practice of reviewing Federal Circuit decisions when "other courts have held or assumed" the contrary, *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 60 (1998), recognizes that conflicts between the Federal Circuit's decisions and those of other circuits on "patent issues" are "useful in identifying questions that merit this Court's attention," *Holmes Group*, 535 U.S. at 839 (Stevens, J., concurring).

[5] In reviewing the totality of the circumstances in connection with a reasonable apprehension analysis, the Eighth and District of Columbia Circuits have accorded weight to the fact that the patentee has previously brought infringement actions. *See United Christian Scientists*, 829 F.2d at 1158 n.25 (noting that "prior record of infringement charges against the declaratory plaintiff or others similarly situated" is one of the factors "which courts have regularly recognized as buttressing a reasonable apprehension"); *Sherwood Med.*, 512 F.2d at 728 (recognizing that patentee's *entire* course of conduct, including past litigation, supported a "reasonable apprehension" of impending litigation).

1982). And while the First Circuit—which considered the question in the context of a dispute over which it had jurisdiction under World Trade Organization procedures—expressly holds that the "reasonable apprehension of suit" standard is not the only way to establish Article III jurisdiction unless "the only controversy surrounds a potential, future lawsuit," that court holds that, even in the absence of such a potential suit, the facts of a particular case may demonstrate that such a controversy exists. *See Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14, 25 (1st Cir. 2001) (citations omitted).

2. It cannot be seriously argued that Apotex's declaratory judgment complaint fails to state an Article III case or controversy under this Court's precedents and the standard articulated by other circuits based on such precedent. There is a concrete legal controversy between Apotex and Pfizer with respect to whether Apotex's generic product infringes Pfizer's patent. Pfizer's listing of the '699 patent in the Orange Book constituted a representation by it that "a claim of patent infringement could reasonably be asserted" against a generic equivalent on the basis of that patent. 21 U.S.C. §§ 355(b)(1), (c)(2). Apotex has alleged that it intends to market a drug that, according to the Orange-Book listing, Pfizer believes will violate its patent. Under the federal patent laws, Apotex's filing of an ANDA challenging the validity or infringement of that patent constitutes a technical act of patent infringement as matter of law. 35 U.S.C. § 271(e)(2). Pfizer has further refused to acknowledge that Apotex's product is non-infringing. In these circumstances, only a suit by Apotex can resolve the controversy.

Nor is there any serious dispute that Apotex has suffered an "injury." Even the Federal Circuit did not doubt in the slightest that Teva had suffered an "injury" in similar circumstances. (Pet. App. 39a-40a). Instead, the *Teva* court deemed the fact that a generic manufacturer "is disadvantaged from a business standpoint" as irrelevant as a matter of law. (*Id.* 40a). Apotex is faced with this very situation here.

The legal dispute that Apotex seeks to resolve has at least two definite, adverse consequences for Apotex that would be remedied by a judgment in its favor—and, indeed, can *only* be remedied by such a judgment. First, Apotex is deterred by the prospect of devastating infringement liability from entering the marketplace. Manufacturers in Apotex's position frequently have massive investments tied up in the development of their generic equivalents by the time that they submit an ANDA. As Judge Mayer recognized in his *Teva* dissent, ANDA applicants such as Apotex "suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic product free from infringement allegations." (Pet. App. 49a). "[D]eclaratory judgment actions serve an important role because the [FTC's] Generic Drug Study showed that no generic applicant entered the market prior to a district court decision addressing the patents that, at the time of its application, were listed in the Orange Book." (FTC Panel Br. 8 n.9 (citation omitted)).

Second, even if Apotex wanted to market its drug before receiving patent certainty, the FDA *cannot* approve Apotex's generic equivalent for at least 180 days after the expiration of Pfizer's first patent, unless Apotex secures an earlier favorable patent judgment. (*See* FTC Panel Br. 2). Thus, "[t]he controversy is real and immediate, and is between adverse parties, because Pfizer's conduct creates a bottleneck that just as surely delays [Apotex] from receiving FDA approval to market a product as if Pfizer had won a preliminary injunction in an infringement suit against [Apotex]." (FTC En Banc Br. 9). "Absent such a decision, [Apotex] (and every other ANDA applicant) instead must wait for its approval until Ivax has marketed its product for 180 days, which will not occur until December 2006, at the earliest. Thus, the only way that [Apotex] can advance the date of the approval of its product is through this litigation. Absent this action, [Apotex] suffers an injury-in-fact from the lost opportunity to bring its product to market during the 180 days." (FTC Panel Br. 21-22).

3. The Federal Circuit's holding that Apotex nonetheless fails to state a justiciable controversy because it does not face an "*imminent* suit" from Pfizer is unsupportable. (*See* Pet. App. 30a). The "pragmatic" concern that gave rise to the Federal Circuit's reasonable apprehension test is completely missing here. *See EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811-12 (Fed. Cir. 1996). That requirement was adopted to "protect[] quiescent patent owners against unwarranted litigation" when they have "done nothing but obtain a patent." *Arrowhead*, 846 F.2d at 736 (citation omitted). The prudential standing rule thereby seeks "to determine whether the need for judicial attention is real and immediate." *BP Chems.*, 4 F.3d at 978 (citation omitted). The rule is "but a pragmatic attempt to give operational guidance against which patentees can structure their conduct, and control their litigation costs, in a fact-specific area of law." (Pet. App. 52a (Gajarsa, J., dissenting)). But in this context, "exercising jurisdiction over this action does not force a lawsuit on a 'quiescent' patent-owner." (FTC Panel Br. 13). To the contrary, as Judge Mayer recognized in his *Teva* dissent, "[b]y listing its patent [in the Orange Book], Pfizer has informed the world that the '699 patent likely precludes anyone from marketing a generic sertraline hydrochloride product until it expires." (*Id.* 46a). Both the district court and the court of appeals recognized that Pfizer—like other brand-name manufacturers in its position—declined to file suit not because of ambivalence about its patent rights, but instead to prevent generic competition. (*See id.* 4a-5a, 40a). Any doubt is resolved by the facts that Pfizer sued Ivax on an indistinguishable claim and refused to grant Apotex any reassurance that Pfizer will not sue Apotex for infringement.

Thus, the Federal Circuit's odd rule that litigation must be imminent "is ill-suited to evaluate an action brought by a subsequent ANDA applicant when that applicant *requires* a court decision so that it can get FDA approval to bring its product to market." (FTC Panel Br. 12). The prudential interest in limiting the burdens of litigation on patent holders is simply overborne in this circumstance.

But even if it otherwise applied, the Federal Circuit's prudential standing rule did not survive Congress's enactment of a specific directive that federal courts shall exercise jurisdiction over suits such as this to the fullest extent consistent with the Constitution. *See* 35 U.S.C. § 271(e)(5); *Raines v. Byrd*, 521 U.S. 811, 820 n.3 (1997) (recognizing that Congress may eliminate prudential standing rules by statute).

II. The Question Presented Is Vitally Important To Pharmaceutical Competition.

Apotex's petition also should be granted because it presents a question of fundamental importance to competition in the pharmaceutical industry and, accordingly, to the American public that relies so heavily on lower-priced generic drugs to combat the skyrocketing costs of healthcare.

1. Because the Federal Circuit has exclusive jurisdiction over patent disputes, the ruling below governs every attempt in the nation by generic drug companies to resolve patent disputes with brand-name manufacturers. The decision provides a roadmap for brand-name manufacturers to preclude litigation of all such disputes. "No incumbent will ever make the threat [of litigation], if it can simply ride out the term in the listed patent." (Pet. App. 59a (Gajarsa, J., dissenting)).

As this Court has previously recognized, Congress enacted those provisions of the Hatch-Waxman scheme at issue here "to enable new drugs to be marketed more cheaply and quickly . . . ." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). "Quite obviously, the purpose of these provisions] is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend." *Id.* at 678. And just as the "scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement" (*id.*), it "will not work" if the patent holder can prevent generic manufacturers from establishing in court that there has been no infringement on the pioneer's patents.

The FTC concurs that "[d]eclaratory judgment actions by ANDA applicants concerning listed patents play a vital role in the Hatch-Waxman regime," (FTC Panel Br. 12), and, as a consequence, "further[] competitive pharmaceutical markets and in lowering health care costs," (FTC En Banc Br. 2). Indeed, the FTC concludes that "even a modest delay in the entry of subsequent ANDA applicants may impose substantial costs on consumers because competition among generic manufacturers has a strong impact on the price of a drug." (FTC Panel Br. 8).

Amicus GPhA has surveyed its membership to determine the significance of the very question presented here. The responses confirm that the Federal Circuit's decision fundamentally affects competition throughout the pharmaceutical industry. The survey conclusively established two facts: (i) the FTC and the dissenting judges in *Teva* correctly concluded that these circumstances present a concrete controversy; and (ii) the number of drugs affected by the decision is large and constantly growing.

GPhA's members report that they regularly defer entering the market until they can litigate the question of patent infringement to at least a district court judgment.[6] By not bringing suit, brand companies perpetuate paralyzing uncertainty that allows them to continue selling their branded

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[6] To cite just a few examples:

- Eon Labs launched its equivalent to Sporanox® only after a favorable district court judgment. *Janssen Pharm. N.V. v. Eon Labs Mfg., Inc.*, 374 F. Supp. 2d 263 (E.D.N.Y. 2004).
- Geneva launched its equivalent to Augmentin® only after a favorable district court judgment; other manufacturers then followed suit. *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 213 F. Supp. 2d 597 (E.D. Va. 2002), *aff'd*, 349 F.3d 1373 (Fed. Cir. 2003).
- Barr Labs launched its equivalent to Mircette® only after a favorable district court judgment. *Bio-Technology Gen. Corp. v. Duramed Pharms., Inc.*, 174 F. Supp. 2d 229, 232 (D.N.J. 2001).
- Conversely, Eon Labs has been precluded from litigating with respect to its generic equivalent to Pfizer's Accupril® and has not entered the market despite having final approval.

drugs at monopoly prices. The decision below is particularly pernicious because it is the drugs that the public most frequently uses—and that give rise to the greatest possible infringement liability—that will suffer reduced competition. Infringement damages for blockbuster drugs such as Zoloft® (generating annual revenues for Pfizer well in excess of $2 billion) would ruin most generic companies.

GPhA's members also report that the ruling below would have a sweeping effect. Generic manufacturers regularly seek to market generic equivalents and represent in their ANDAs that the patents listed in connection with the innovator drug are either invalid or will not be infringed. The most recent data published by the FDA indicates that generic manufacturers have filed such ANDA certifications for over 300 drugs. *See* http://www.fda.gov/cder/ogd/ppiv.htm (last visited Mar. 29, 2006). More than seventy of these certifications were submitted in the last two-and-a-half years alone. *Id.* Many of those drugs are likely to present patent issues that ought to be resolved promptly but, under the Federal Circuit's ruling, cannot be.

The following examples illustrate the broad sweeping effect of the *Teva* ruling:

- The ruling does not merely affect Apotex with respect to Zoloft®. In addition to Apotex and Teva, Dr. Reddy's filed an ANDA seeking to market generic Zoloft® products and brought a similar declaratory judgment action. That action was dismissed on the same ground as the Federal Circuit's ruling here. *See Dr. Reddy's Labs., Ltd. v. Pfizer Inc.*, No. Civ.A.03-CV-726(JAP), 2003 WL 21638254 (D.N.J. July 8, 2003).

- The ruling also affects numerous other drugs. For example, generic manufacturers have attempted to litigate the patent validity/non-infringement of generic equivalents to Pfizer's Accupril® (which generates nearly $600 million in annual U.S. sales). More specifically, two generic manufacturers that filed ANDAs for Accupril® sought a declaratory judgment when Pfizer failed to sue. Those cases were

dismissed on the same rationale as the *Teva* decision. *Tor-Pharm, Inc. v. Pfizer Inc.*, No. Civ.03-990-SLR, 2004 WL 1465756 (D. Del. June 28, 2004), *vacated and remanded by* 125 Fed. Appx. 987 (Fed. Cir. 2005)[7]; *Mut. Pharm. Co. v. Pfizer Inc.*, 307 F. Supp. 2d 88 (D.D.C. 2004).

• Teva and Mylan Laboratories submitted ANDAs with respect to Merck & Co.'s Proscar®. Merck did not file suit against either. Relying on the *Teva* decision, the district court dismissed Mylan's declaratory judgment action. *Mylan Pharms. Inc. v. Merck & Co.*, No. Civ. 1:05-cv-1416, 2005 WL 2850137 (M.D. Pa. Oct. 28, 2005).

2. By substantially impeding generic competition, the Federal Circuit's ruling will directly injure consumers and the public health. Because generic drugs are generally sold for a fraction of the prices of their brand-name counterparts, the substitution of generic drugs for brand-name drugs results in billions of dollars in savings each year.[8] A one-percent increase in the substitution of generic drugs for brand-name drugs could result in a savings of up to $2 billion per year, while the widespread substitution of generic drugs for brand-name drugs whenever possible could save U.S. consumers as much as $17 billion per year. Dep't of Health & Human Services Task Force on Drug Importation,

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[7] Apotex appealed that district court decision. Upon learning that the panel in the case included two judges (Mayer and Gajarsa) who had in previous cases expressed the view that a case or controversy exists in these circumstances, and before the denial of *en banc* review in *Teva*, Pfizer granted Apotex a covenant not to sue, rendering Apotex's appeal moot. *See Apotex Inc. v. Pfizer Inc.*, 125 Fed. Appx. 987 (2005).

[8] *See* Food and Drug Administration, *FDA White Paper: New FDA Initiative on Improving Access to Generic Drugs* (June 12, 2003), *available at* http://www.fda.gov/oc/initiatives/generics/whitepaper.html (reporting that average price of a brand-name drug is $72, compared with $17 for its generic counterpart); Statement of the FTC on *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements*, Before the Committee on the Judiciary of the United States Senate (May 24, 2001), *available at* http://www.ftc.gov/os/2001/05/pharmstmy.htm (estimating that consumers saved $8 to $10 billion in 1994 by substituting generics for brand-names).

REPORT ON PRESCRIPTION DRUG IMPORTATION 68 (Dec. 2004), *available at* http://www.hhs.gov/importtask force/Report1220.pdf; Steven Findlay, *Easy Way To Cut Costs Of Drugs: Generics*, USA TODAY, May 13, 2004, at 23A.

Access to generic pharmaceuticals thus is "perhaps the single most important route to lower personal and national drug costs during the next decade." Findlay, *supra*. Indeed, the cost savings created by generic pharmaceuticals translates directly into improved public health and, accordingly, lives saved. As the FDA Commissioner has explained, generic drugs "are an increasingly important way to provide the American people with safe, effective and affordable medical treatment." *Generics: FDA Announces Measures To Improve Generic Drug Access*, DRUG WEEK, Mar. 26, 2004, at 231; *see also* The National Institute For Health Care Management (NIHCM), *A Primer: Generic Drugs, Patents and the Pharmaceutical Marketplace* 19 (June 2002) ("[t]he advent of [the generic equivalent of the anti-depressant Prozac]" may help rectify the "persistent under-diagnosis and under-treatment of depression in the U.S."), *available at* http://www.nihcm.org/finalweb/GenericsPrimer.pdf.

High prescription costs are a significant—and at times, insuperable—barrier to proper treatment for many Americans, particularly the elderly. *See Generics Key To Cost Control*, UPI, May 19, 2005 ("the No. 1 reason why patients do not take their medicine is because it is too expensive"); AARP, *Prescription Drug Costs And The Role Of Generic Drugs: Public Opinion Among American Aged 45 and Older* 2 (Oct. 1, 2002) ("[N]early one in four Americans 45 and older (24%) reported *not* being able to afford a prescription drug because no generic version was available."), *available at* http://assets.aarp.org/rgcenter/health/rxgeneric. pdf.

CONCLUSION

The petition for a writ of certiorari should be granted or, at a minimum, the Court should invite the Solicitor General and the Federal Trade Commission to file briefs expressing the views of the United States.

Respectfully submitted,

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